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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/524,247	06/23/2017		2660	DEXCOM.394PR		

CONFIRMATION NO. 9556

CORRECTED FILING RECEIPT

68851
KNOBBE, MARTENS, OLSON & BEAR, LLP
DEXCOM, INC.
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Date Mailed: 04/20/2018

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

John Michael Gray, San Diego, CA;
Jennifer Blackwell, San Diego, CA;
Paul V. Neale, San Diego, CA;
Justen Deering England, San Francisco, CA;
Andrew Joncich, Madison, WI;
Cameron Brock, San Francisco, CA;
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Christian Michael Andre George, San Diego, CA;
Daniel E. Apacible, Chula Vista, CA;
John Charles Barry, San Diego, CA;
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Philip Thomas Pupa, San Diego, CA;
Timothy Joseph Goldsmith, San Diego, CA;
Jonathan Bodnar, Keller, TX;
Neal Davis Johnston, Dallas, TX;
Maria Noel Brown Wells, San Diego, CA;
Kenneth Pirondini, San Diego, CA;
Andrew Michael Reinhardt, Santee, CA;

Applicant(s)

DexCom, Inc., San Diego, CA

Power of Attorney:
Rose Thiessen--40202

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 04/19/2018

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/524,247**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
Title

TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign

patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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62/524,247	06/23/2017		2660	DEXCOM.394PR		

CONFIRMATION NO. 9556
UPDATED FILING RECEIPT

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KNOBBE, MARTENS, OLSON & BEAR, LLP
DEXCOM, INC.
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IRVINE, CA 92614

OC000000097871281

Date Mailed: 03/08/2018

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John Michael Gray, San Diego, CA;
Jennifer Blackwell, San Diego, CA;
Paul V. Neale, San Diego, CA;
Justen Deering England, San Francisco, CA;
Andrew Joncich, Madison, WI;
Cameron Brock, San Francisco, CA;
Peter C. Simpson, Cardiff by the Sea, CA;
Thomas Metzmaker, San Diego, CA;
Neel Narayan, Carlsbad, CA;
Mark Douglas Kempkey, Vista, CA;
Patrick John Castagna, San Diego, CA;
Warren Terry, Poway, CA;
Jason Halac, San Diego, CA;
Christian Michael Andre George, San Diego, CA;
Daniel E. Apacible, Chula Vista, CA;
John Charles Barry, San Diego, CA;
Joseph J. Baker, Vista, CA;
Philip Thomas Pupa, San Diego, CA;
Timothy Joseph Goldsmith, San Diego, CA;
Jonathan Bodnar, Keller, TX;
Neal Davis Johnston, Dallas, TX;
Maria Noel Brown Wells, San Diego, CA;
Kenneth Pirondini, San Diego, CA;
Andrew Michael Reinhardt, Santee, CA;

Applicant(s)

DexCom, Inc., San Diego, CA

Power of Attorney:
Rose Thiessen--40202

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

Projected Publication Date: None, application is not eligible for pre-grant publication
Non-Publication Request: No
Early Publication Request: No
Title

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this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
62/524,247	06/23/2017	John Michael Gray	DEXCOM.394PR

CONFIRMATION NO. 9556

68851
KNOBBE, MARTENS, OLSON & BEAR, LLP
DEXCOM, INC.
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FOURTEENTH FLOOR
IRVINE, CA 92614

37 CFR 1.48(d)
ACKNOWLEDGEMENT LETTER

OC000000097871284

Date Mailed: 03/08/2018

NOTICE OF ACCEPTANCE OF REQUEST UNDER 37 CFR 1.48(d)

This is in response to the applicant's request under 37 CFR 1.48(d) submitted on 07/07/2017.

">The request under 37 CFR 1.48(d) to correct the inventorship, to correct or update the name of an inventor, or to correct the order of names of joint inventors is accepted.

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**.

/mmasfaw/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	John Michael Gray
App. No.	:	62/524247
Filed	:	June 23, 2014
For	:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
Examiner	:	---
Art Unit	:	---
Conf. No.	:	9556

REQUEST UNDER 37 CFR 1.48(d) TO CORRECT OR UPDATE INVENTOR'S NAME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.48(d), this Request is being made to correct errors in the names of inventors Neel Narayan Shah (filed as Neel Shah) and Jonathan Bodnar (filed as Jon Bodnar) in the above-referenced application.

The legal names of the inventors are:

John Michael Gray

Jennifer Blackwell

Paul V. Neale

Justen Deering England

Andrew Joncich

Cameron Brock

Peter C. Simpson

Thomas Metzmaker

Neel Narayan Shah

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Mark Douglas Kempkey

Patrick John Castagna

Warren Terry

Jason Halac

Christian Michael Andre George

Daniel E. Apacible

John Charles Barry

Joseph J. Baker

Philip Thomas Pupa

Timothy Joseph Goldsmith

Jonathan Bodnar

Neal Davis Johnston

Maria Noel Brown Wells

Kenneth Pirondini

Andrew Michael Reinhardt This Request is accompanied by:

1. An Application Data Sheet outlining changes being made to inventorship;
2. Fee as directed under 37 CFR 1.17(i) for large entity.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 7, 2017

By: /Rose M. Thiessen/
Rose M. Thiessen
Registration No. 40,202
Attorney of Record
Customer No. 68851
(858) 707-4000

26266966
070717

APPLICATION DATA SHEET

Application Information

Application Number:	62/524247
Filing Date:	June 23, 2017
Application Type:	Regular
Subject Matter:	Utility
Title:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
Attorney Docket Number:	DEXCOM.394PR

Inventor Information

1

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Postal or Zip Code:	92121

9

Status:	Full Capacity
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Family Name:	~~Shah~~ Shah
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State or Province:	CA
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Postal or Zip Code:	92121

10

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Country:	US
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12

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Postal or Zip Code:	92121

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Country:	US

Postal or Zip Code:	92121

14

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Postal or Zip Code:	92121

15

Status:	Full Capacity
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16

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Postal or Zip Code:	92121

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Status:	Full Capacity
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State or Province:	CA
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Postal or Zip Code:	92121

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Middle Name:	Thomas

Family Name:	Pupa
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State or Province:	CA
Country:	US
Postal or Zip Code:	92121

19

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State or Province:	CA
Country:	US
Postal or Zip Code:	92121

20

Status:	Full Capacity
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Family Name:	~~Bodnar~~ Bodnar
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Country of Residence:	US

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City:	San Diego
State or Province:	CA
Country:	US
Postal or Zip Code:	92121

21

Status:	Full Capacity
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Family Name:	Johnston
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Country of Residence:	US
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City:	San Diego
State or Province:	CA
Country:	US
Postal or Zip Code:	92121

22

Status:	Full Capacity
Given Name:	Maria
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Family Name:	Wells
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State or Prov. of Residence:	CA
Country of Residence:	US
Street:	c/o DexCom, Inc., 6340 Sequence Drive
City:	San Diego
State or Province:	CA

Country:	US
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23

Status:	Full Capacity
Given Name:	Kenneth
Family Name:	Pirondini
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Country of Residence:	US
Street:	c/o DexCom, Inc., 6340 Sequence Drive
City:	San Diego
State or Province:	CA
Country:	US
Postal or Zip Code:	92121

24

Status:	Full Capacity
Given Name:	Andrew
Middle Name:	Michael
Family Name:	Reinhardt
City of Residence:	Santee
State or Prov. of Residence:	CA
Country of Residence:	US
Street:	c/o DexCom, Inc., 6340 Sequence Drive
City:	San Diego
State or Province:	CA
Country:	US
Postal or Zip Code:	92121

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Dated: July 7, 2017

By: /Rose M. Thiessen/
Rose M. Thiessen
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Registered Practitioner
Customer No. 68851
(858) 707-4000

26268591

Electronic Patent Application Fee Transmittal

Application Number:	62524247
Filing Date:	23-Jun-2017
Title of Invention:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
First Named Inventor/Applicant Name:	John Michael Gray
Filer:	Rose M. Thiessen/Edgar Compton
Attorney Docket Number:	DEXCOM.394PR

Filed as Large Entity

Filing Fees for Provisional

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($)
Miscellaneous:				
Processing Fee for Provis. applications	1807	1	50	50
		Total in USD ($)		**50**

Electronic Acknowledgement Receipt

EFS ID:	29722450
Application Number:	62524247
International Application Number:	
Confirmation Number:	9556
Title of Invention:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
First Named Inventor/Applicant Name:	John Michael Gray
Customer Number:	68851
Filer:	Rose M. Thiessen/Gustavo Lopez
Filer Authorized By:	Rose M. Thiessen
Attorney Docket Number:	DEXCOM.394PR
Receipt Date:	07-JUL-2017
Filing Date:	23-JUN-2017
Time Stamp:	18:33:51
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$50
RAM confirmation Number	071017INTEFSW18342900
Deposit Account	111410
Authorized User	Gustavo Lopez

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request under Rule 48 correcting inventorship	394PR_CORRINVENT.pdf	21387 3d78c87539042b54f6c04a758e02a50c9e1a1904	no	2
Warnings:					
Information:					
2	Application Data Sheet	394PR_CORRADS.pdf	32974 52fe72d84aad5324d0957f25c384642734750327	no	12
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
3	Fee Worksheet (SB06)	fee-info.pdf	30540 bcf062ec7c007cb9e51d68ff7db1c7624a4ce96e	no	2
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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

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
62/524,247	06/23/2017		2660	DEXCOM.394PR		

CONFIRMATION NO. 9556

FILING RECEIPT

68851
KNOBBE, MARTENS, OLSON & BEAR, LLP
DEXCOM, INC.
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

OC000000092496515

Date Mailed: 07/03/2017

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

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Kenneth Pirondini, San Diego, CA;
Andrew Michael Reinhardt, Santee, CA;

Applicant(s)

DexCom, Inc., San Diego, CA

Power of Attorney:
Rose Thiessen--40202

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

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If Required, Foreign Filing License Granted: 06/30/2017

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 62/524,247**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No
Title

TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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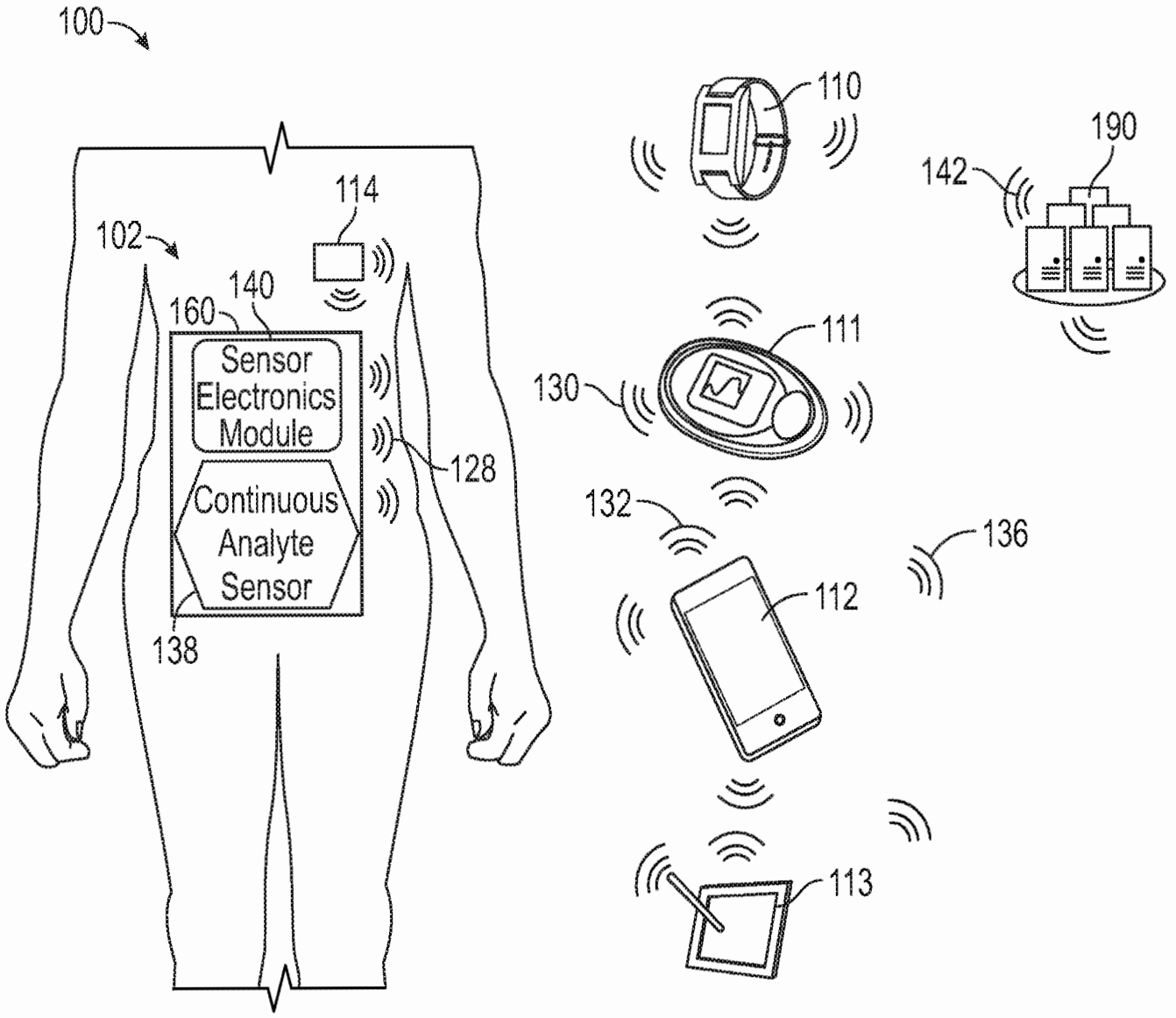

100
102
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Sensor Electronics Module
Continuous Analyte Sensor
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FIG. 1

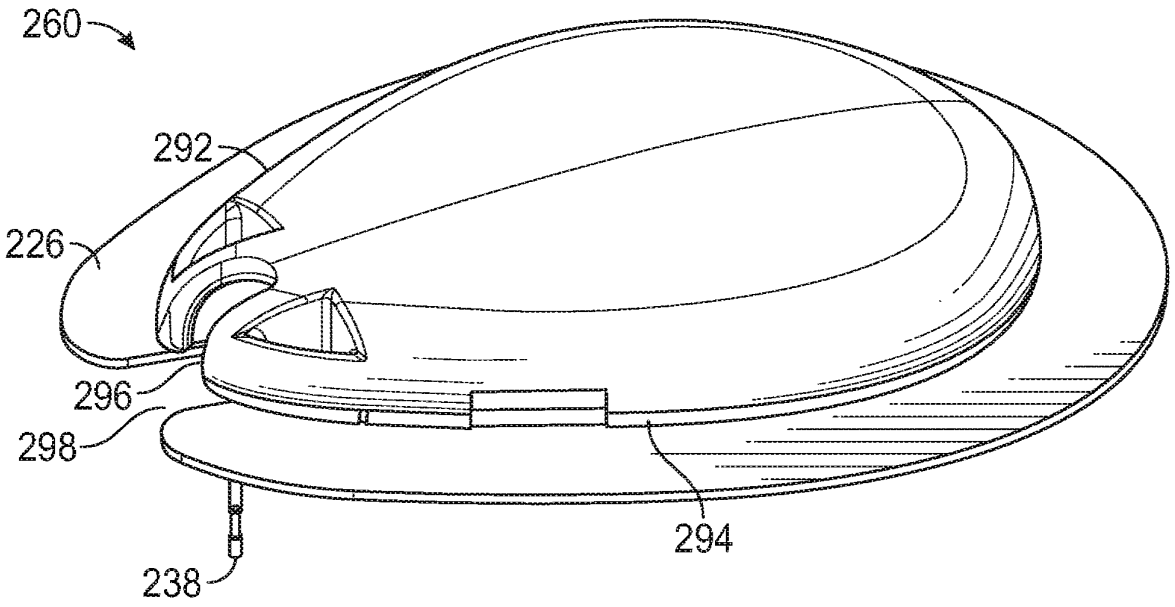


FIG. 2A

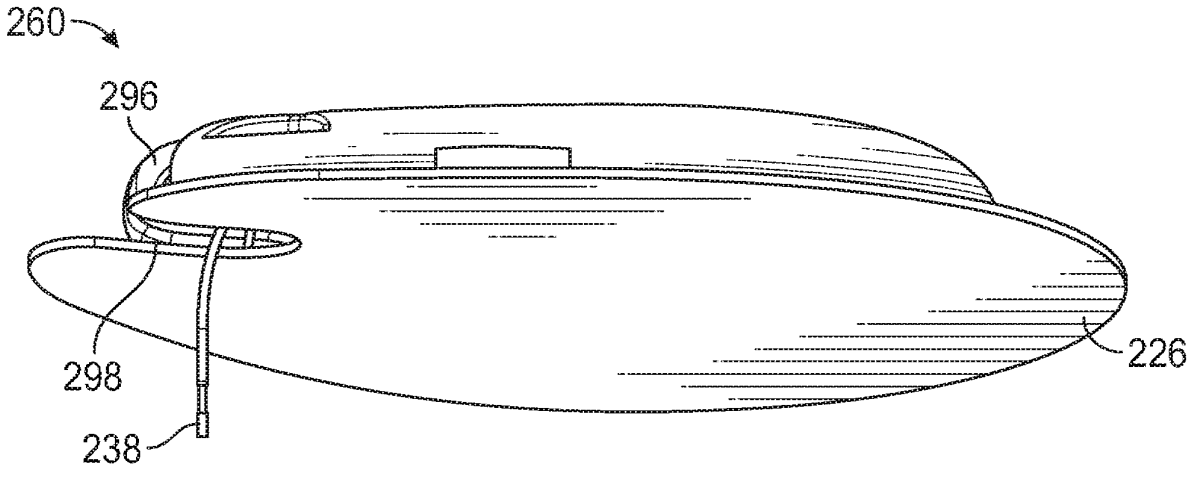


FIG. 2B

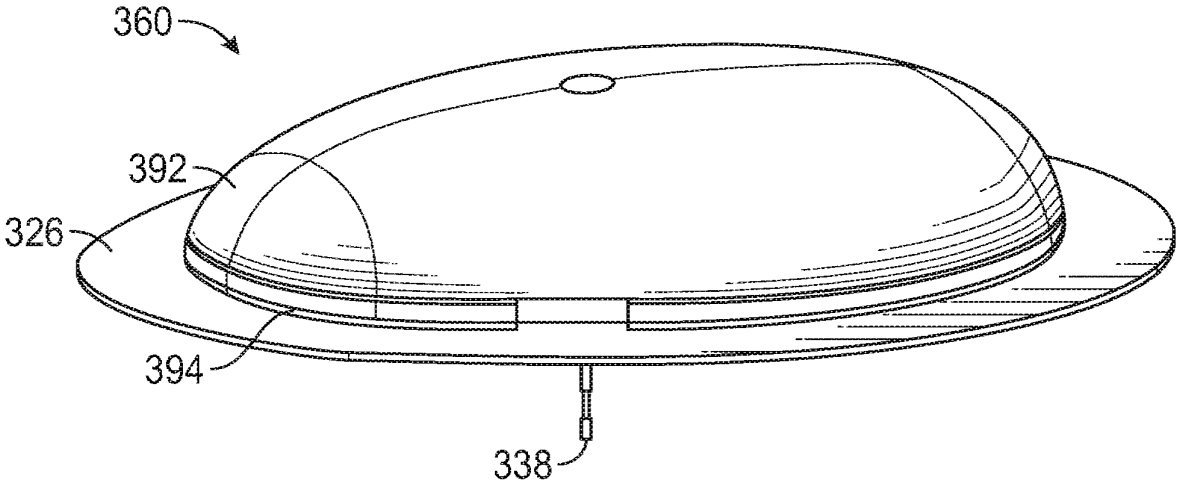


FIG. 3A

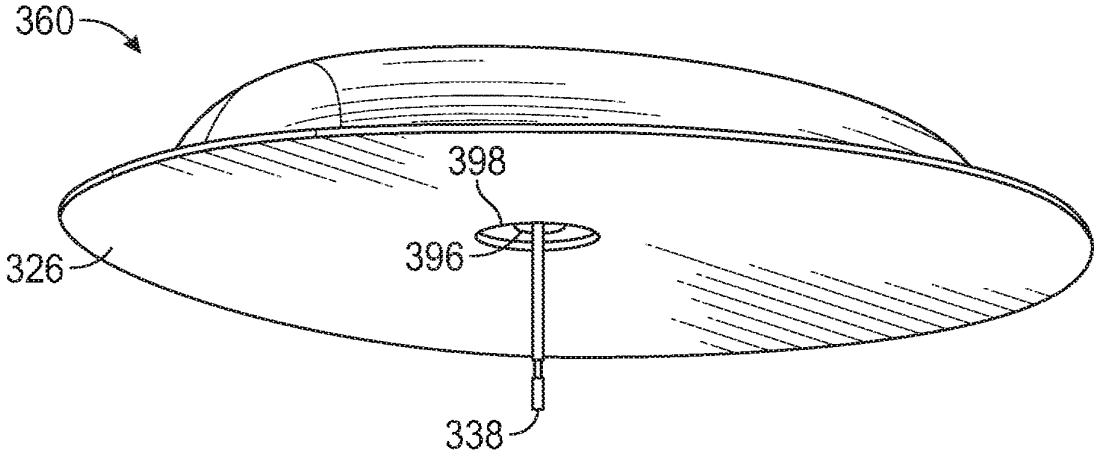


FIG. 3B

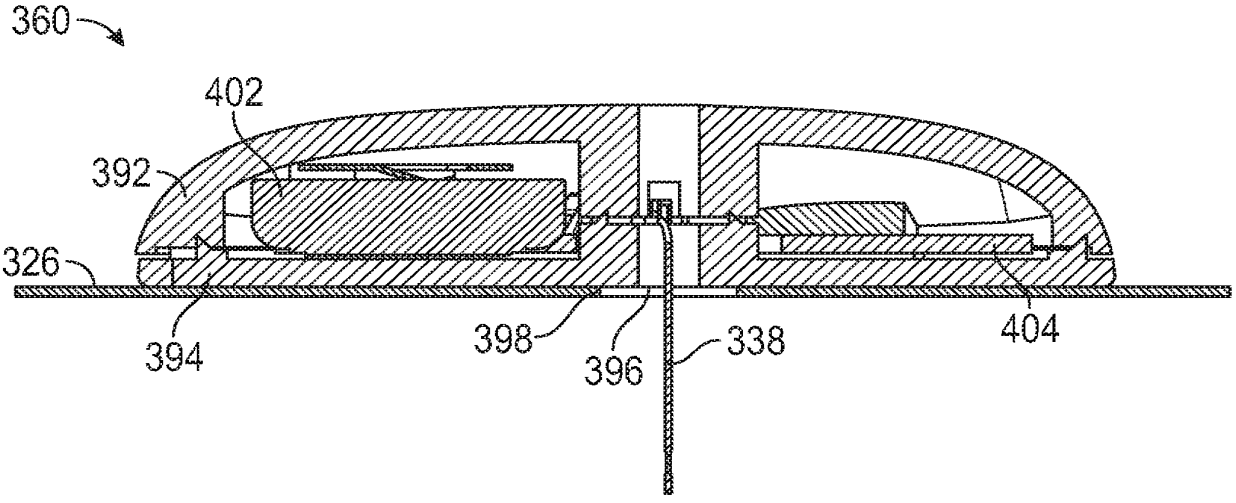


FIG. 4

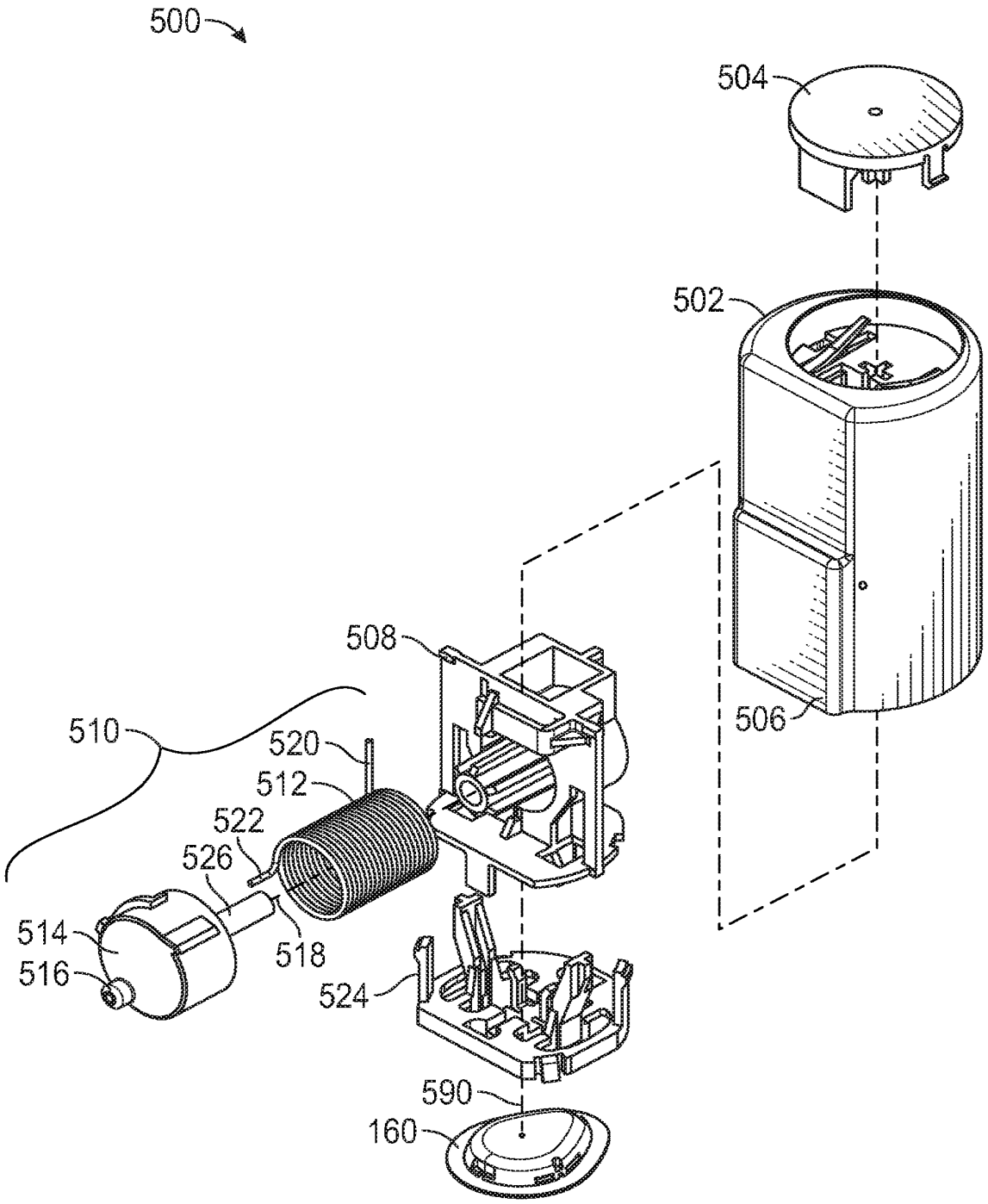


FIG. 5

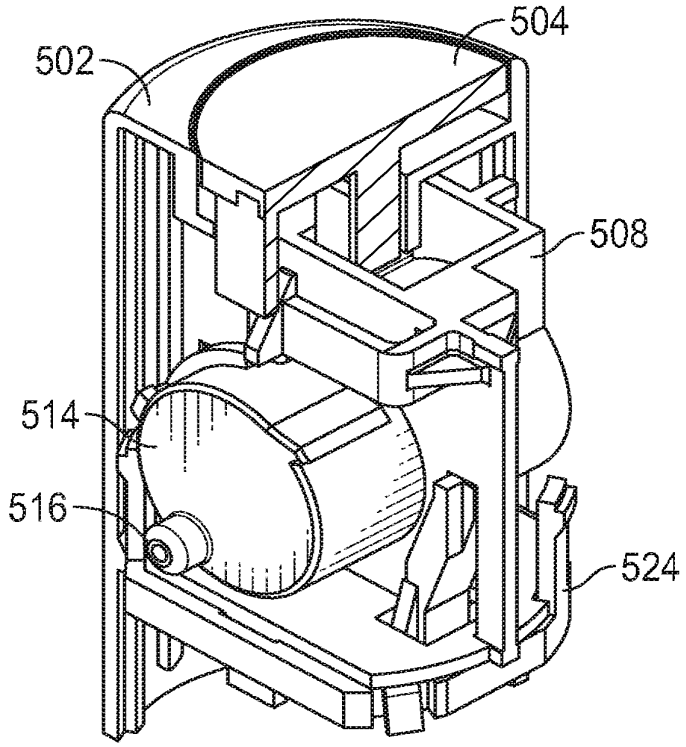


FIG. 6A

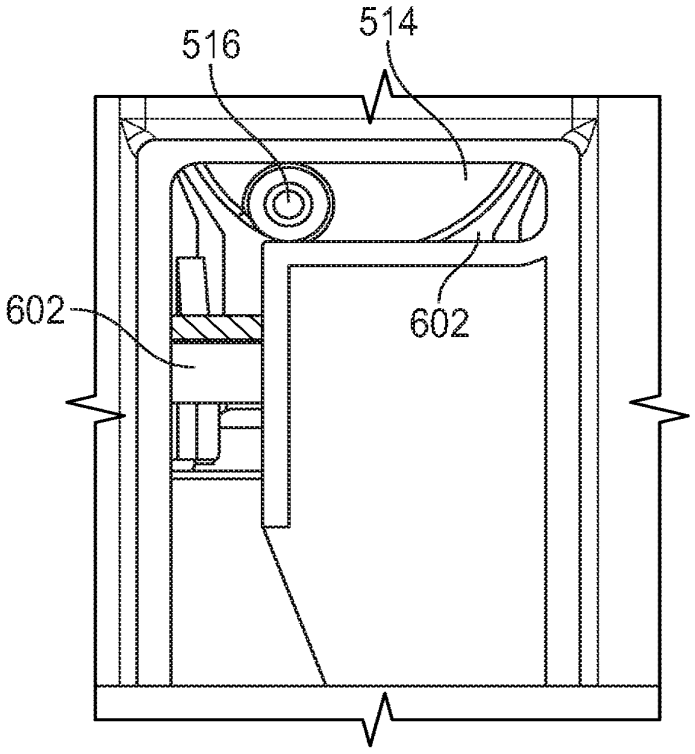


FIG. 6B

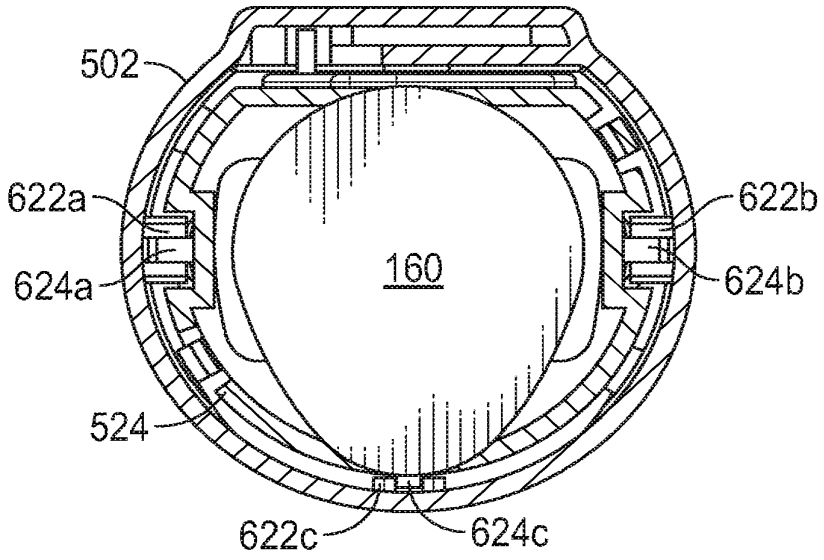


FIG. 6C

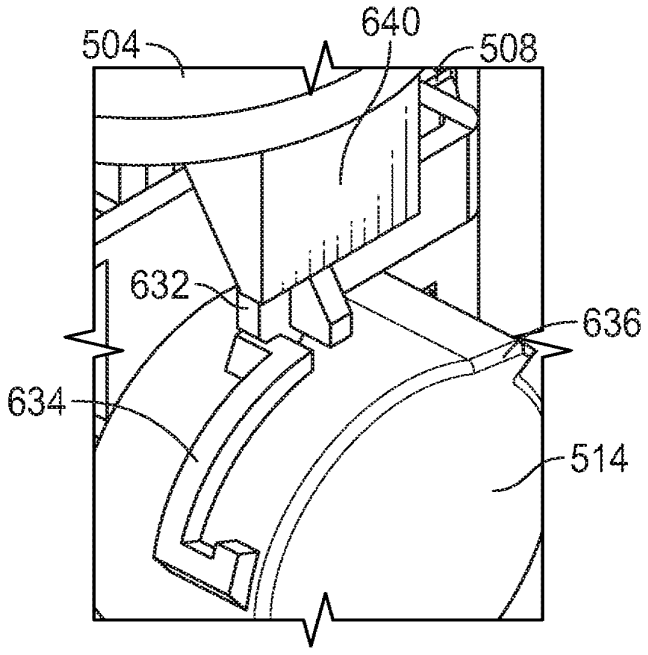


FIG. 6D

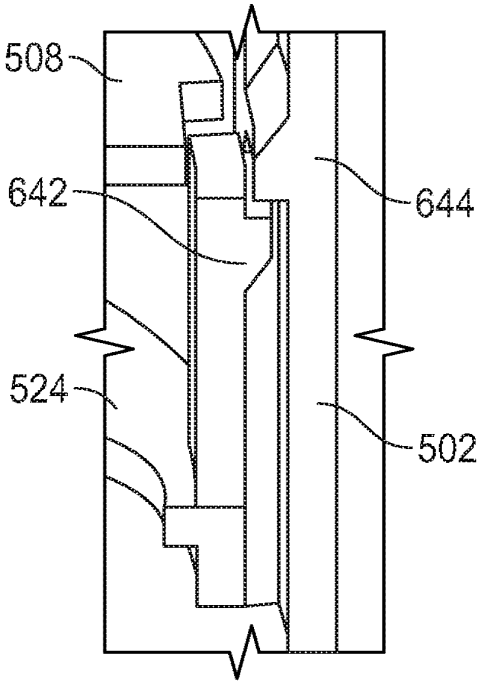


FIG. 6E

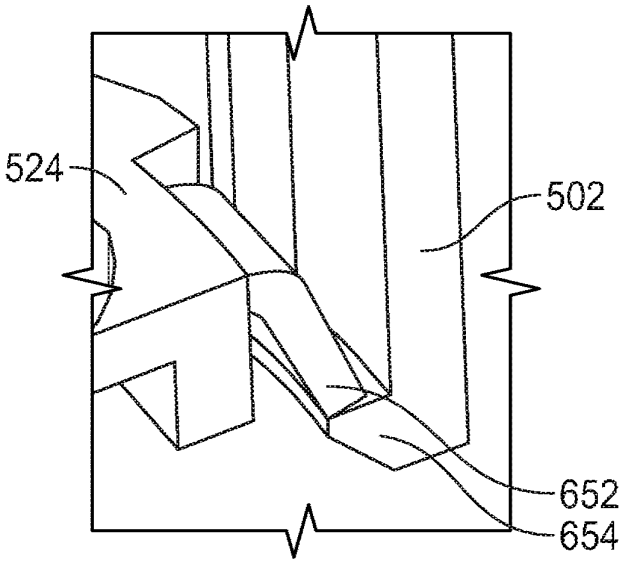


FIG. 6F

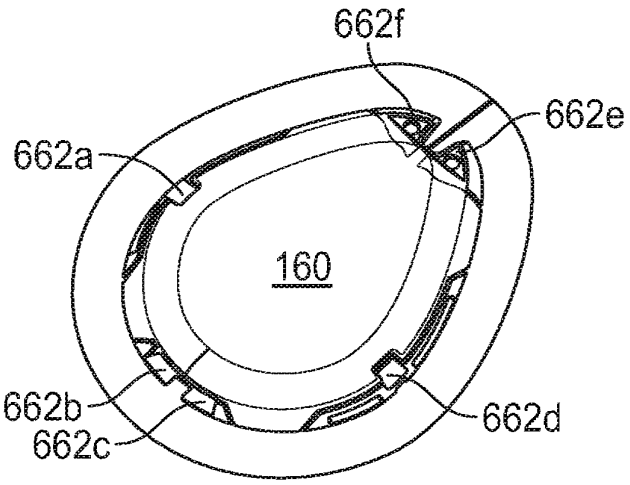


FIG. 6G

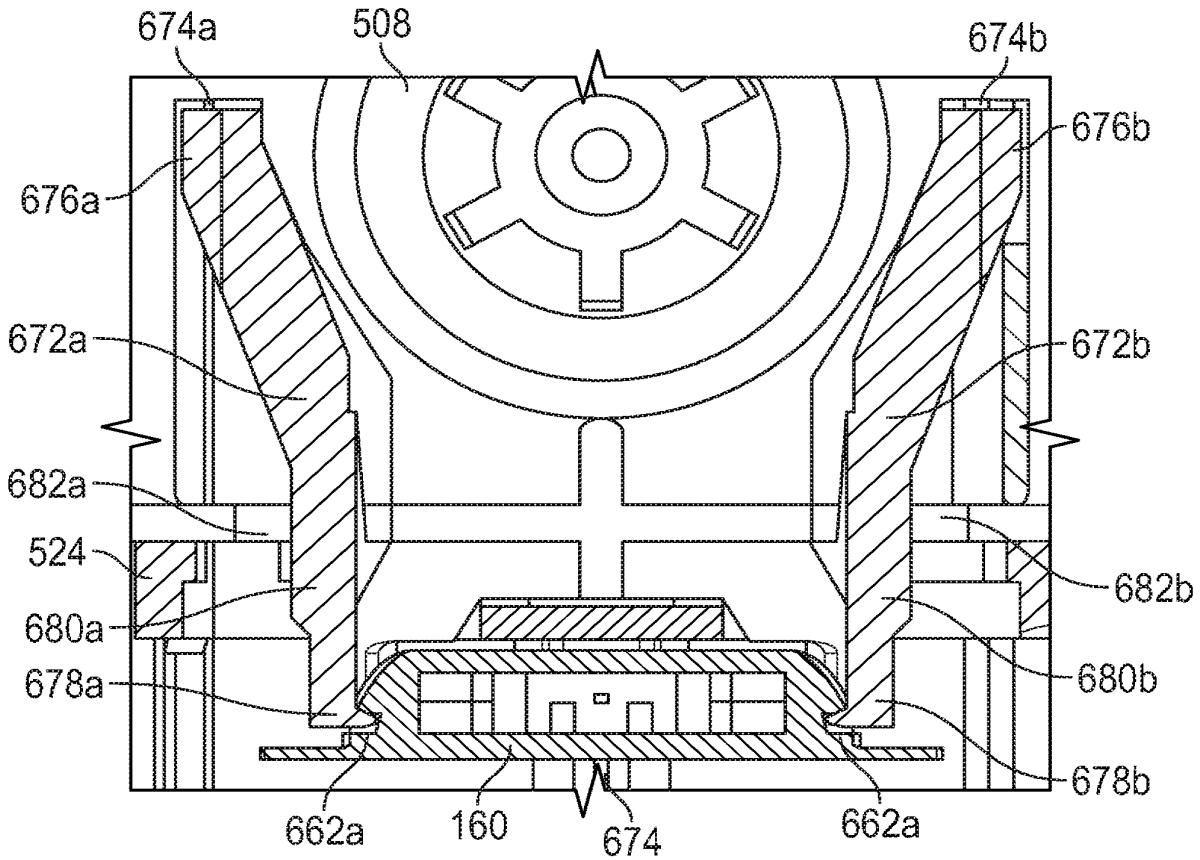


FIG. 6H

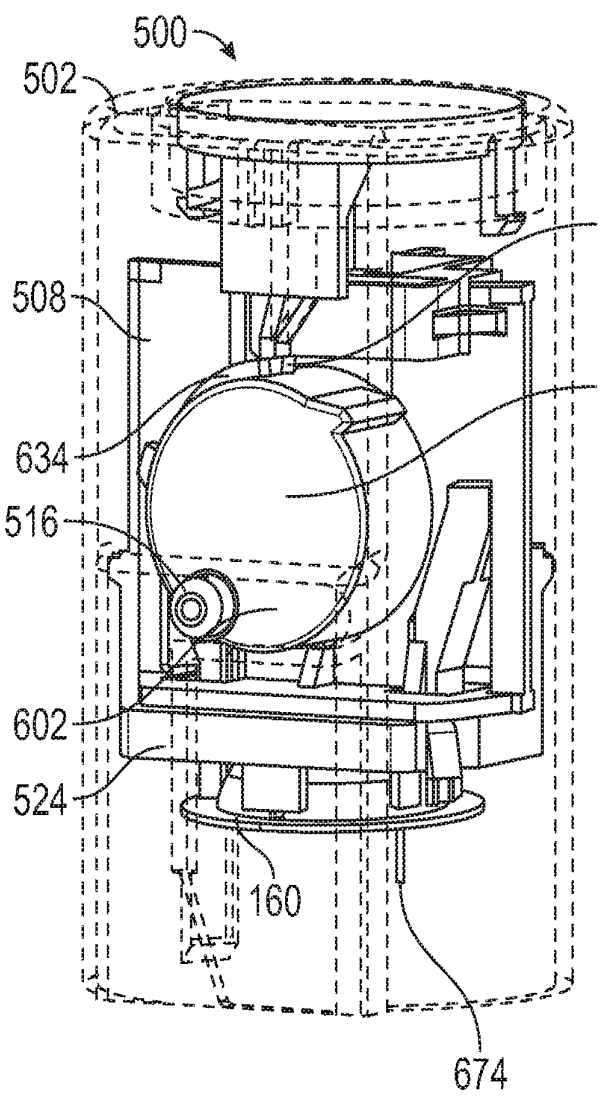


FIG. 7A

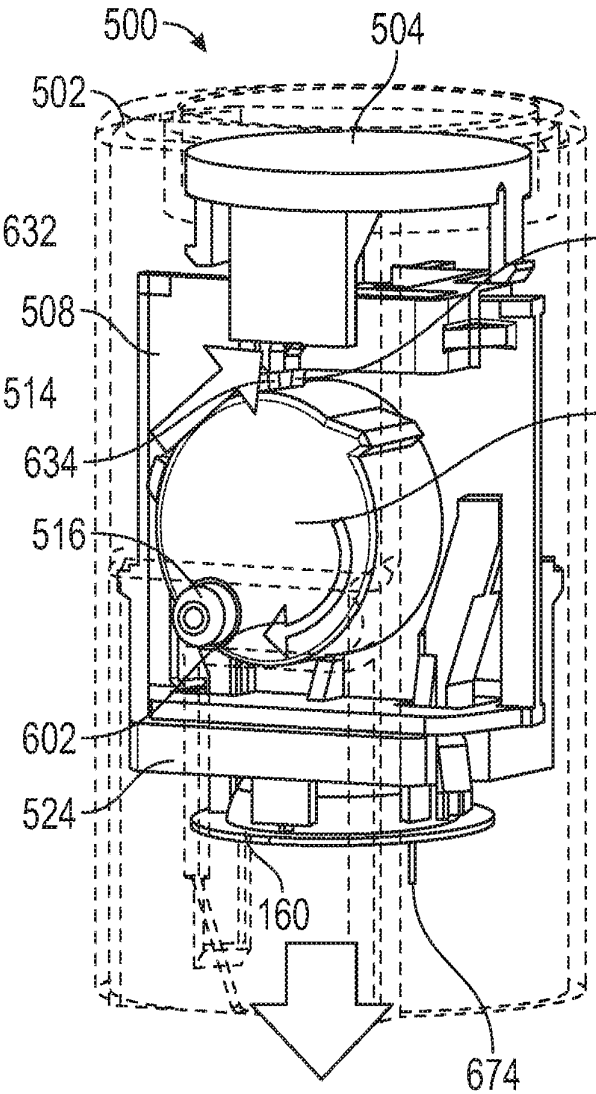


FIG. 7B

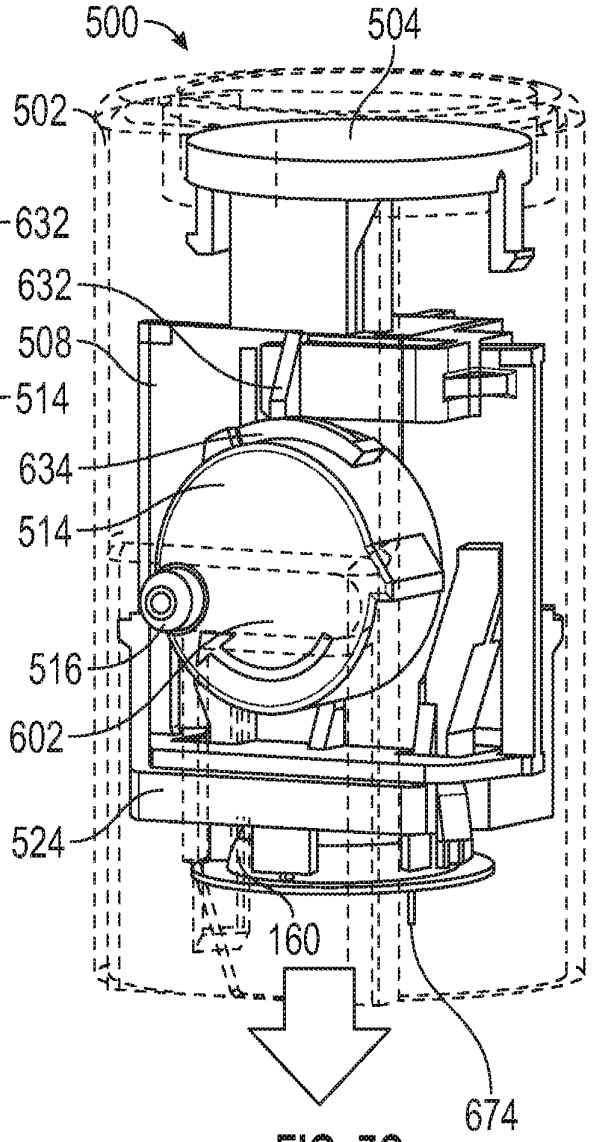


FIG. 7C

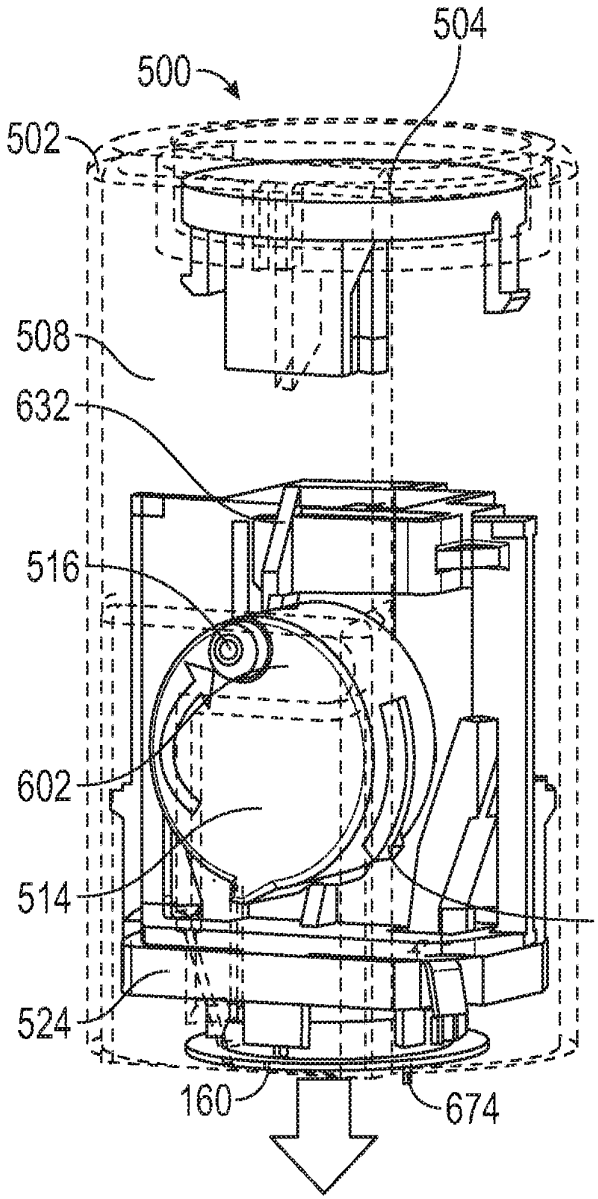


FIG. 7D

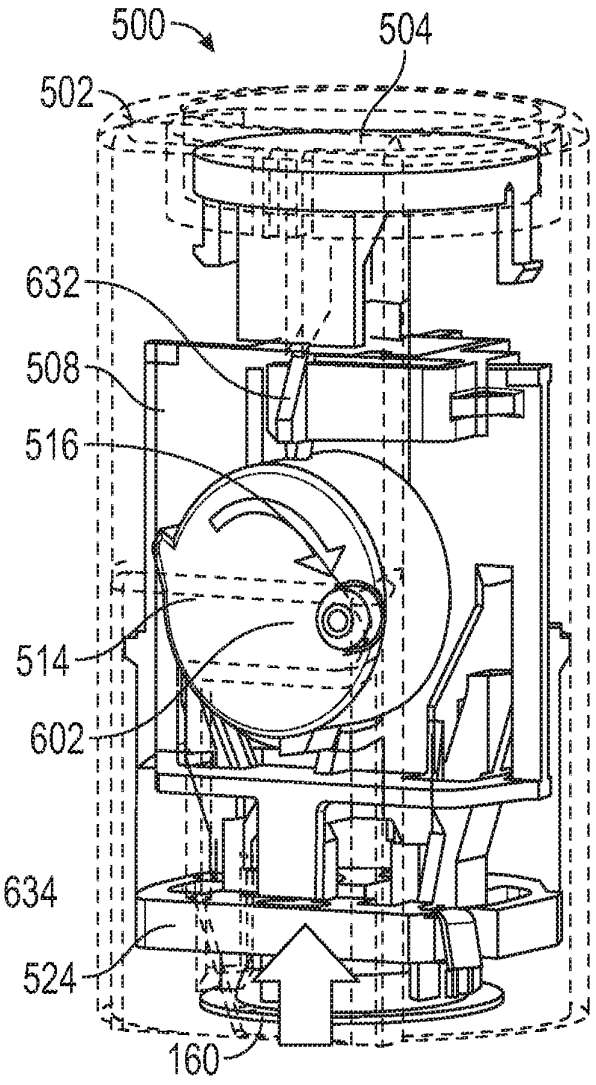


FIG. 7E

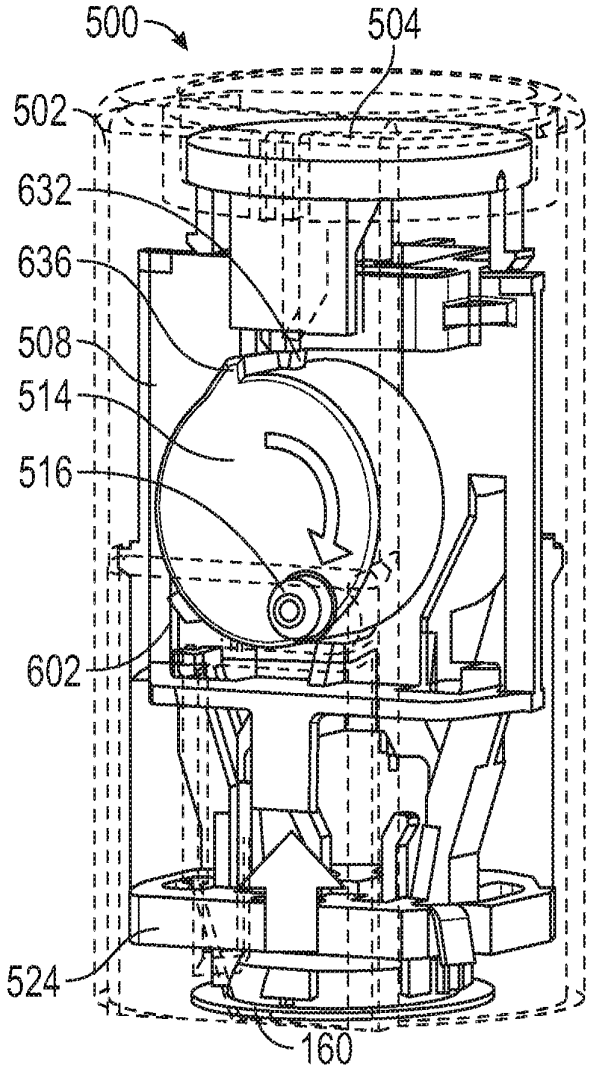


FIG. 7F

Abbott Ex. 1003 - 40/532

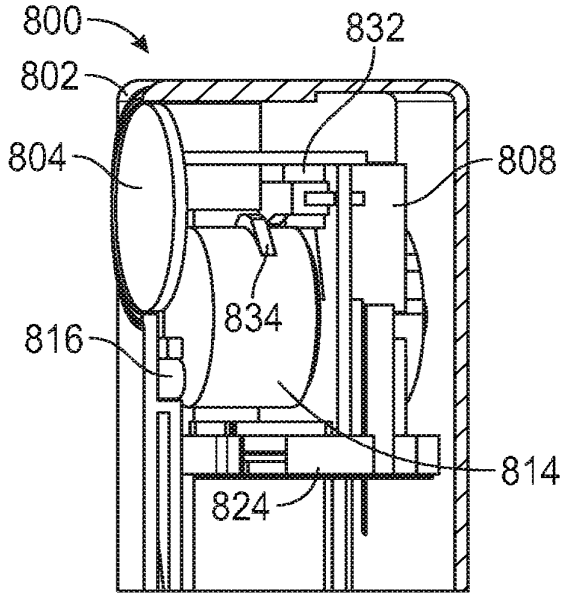


FIG. 8

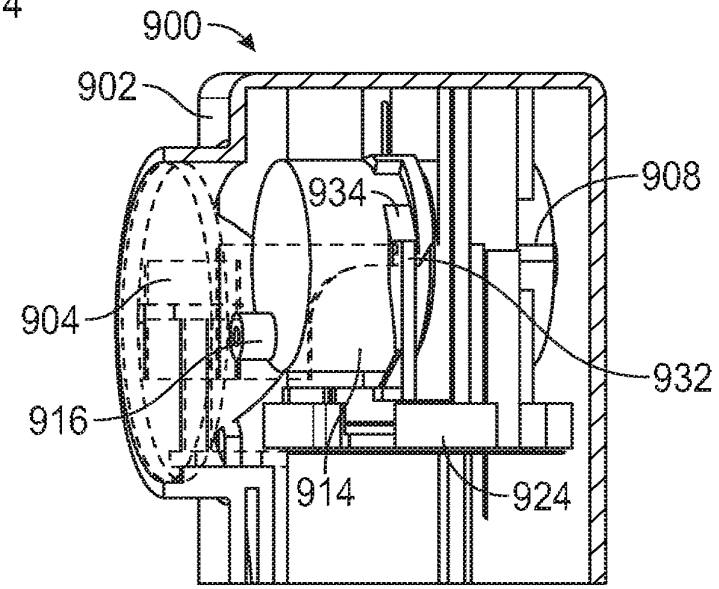


FIG. 9

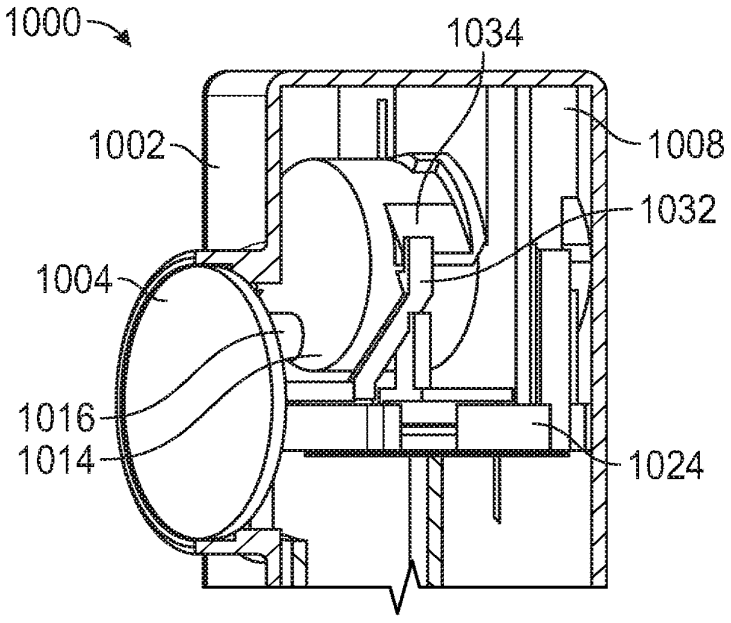


FIG. 10

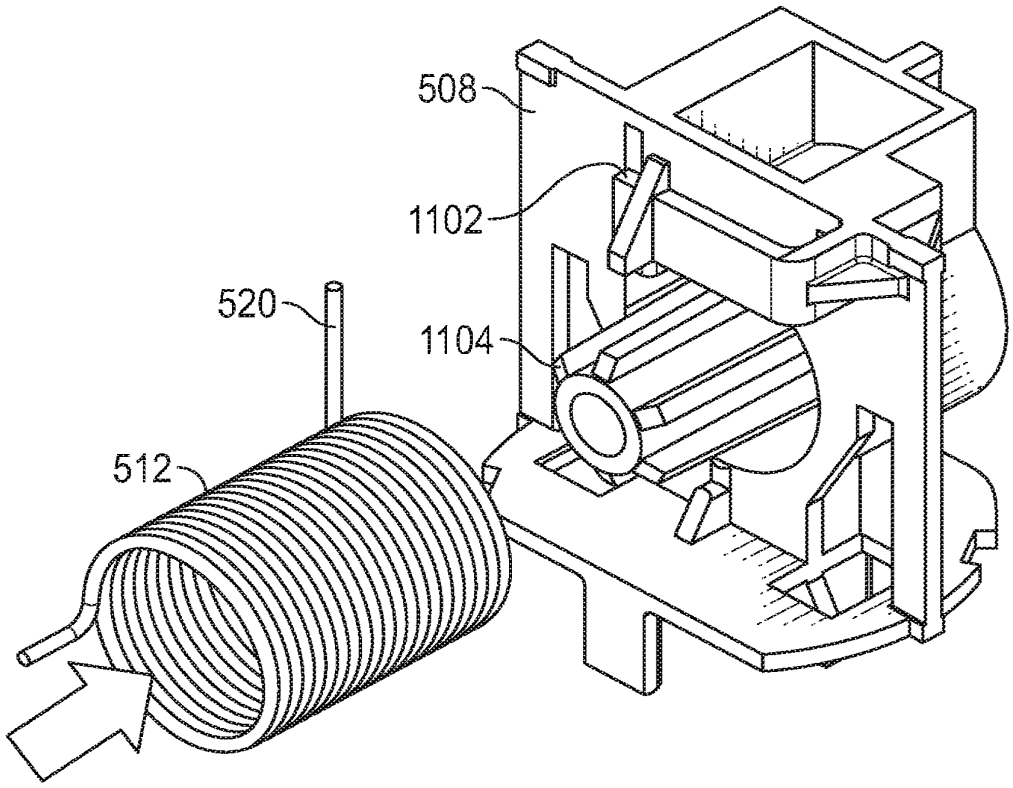


FIG. 11A

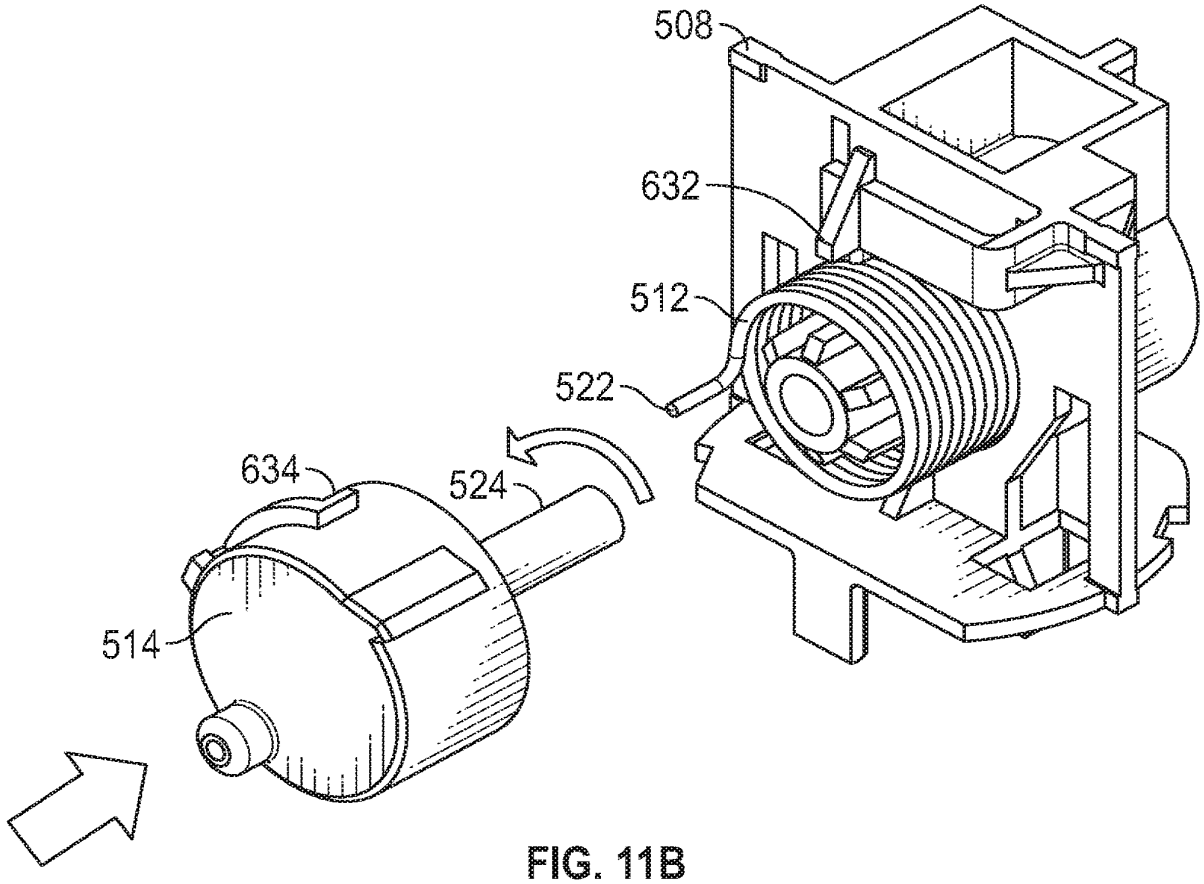


FIG. 11B

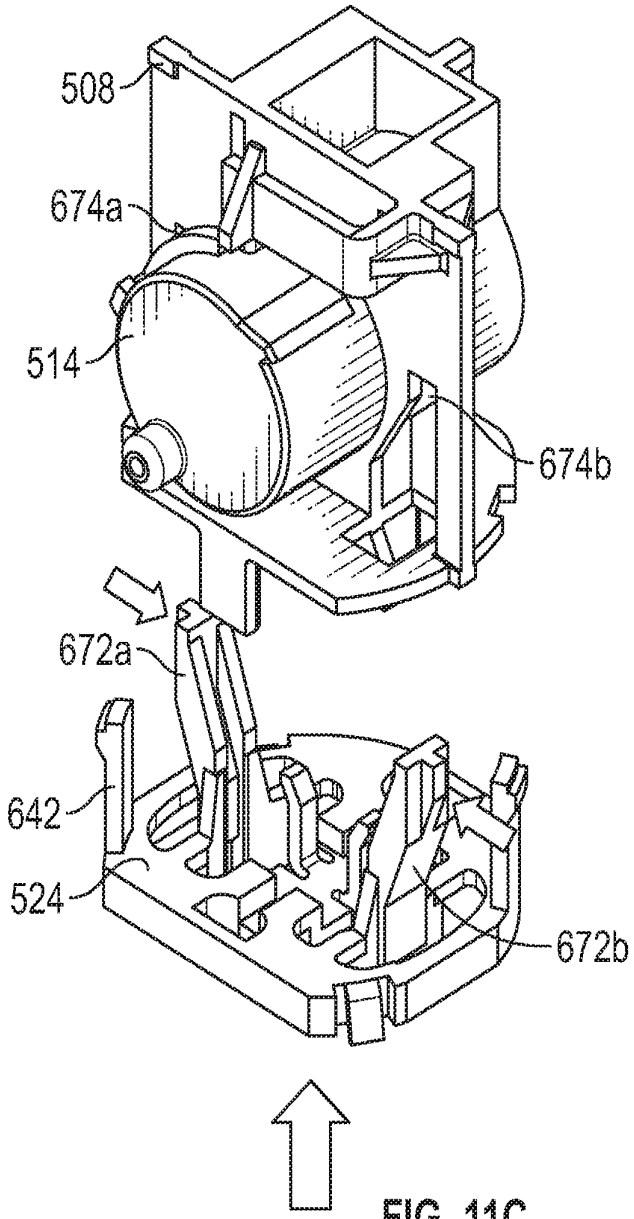


FIG. 11C

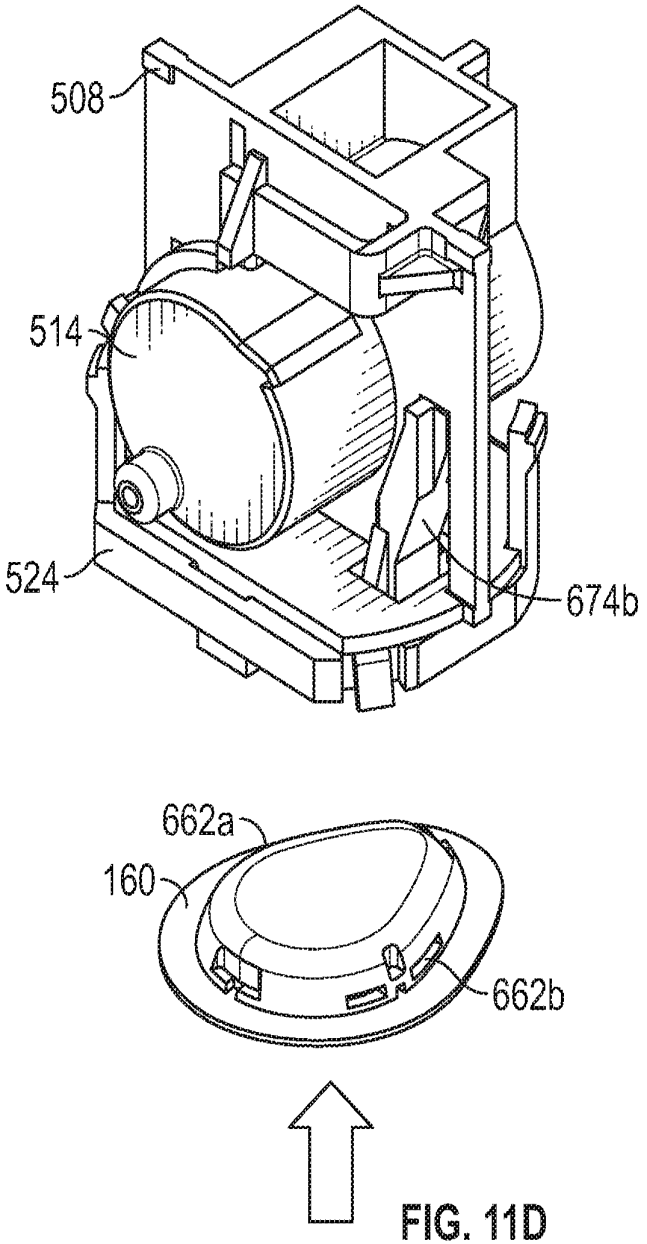


FIG. 11D

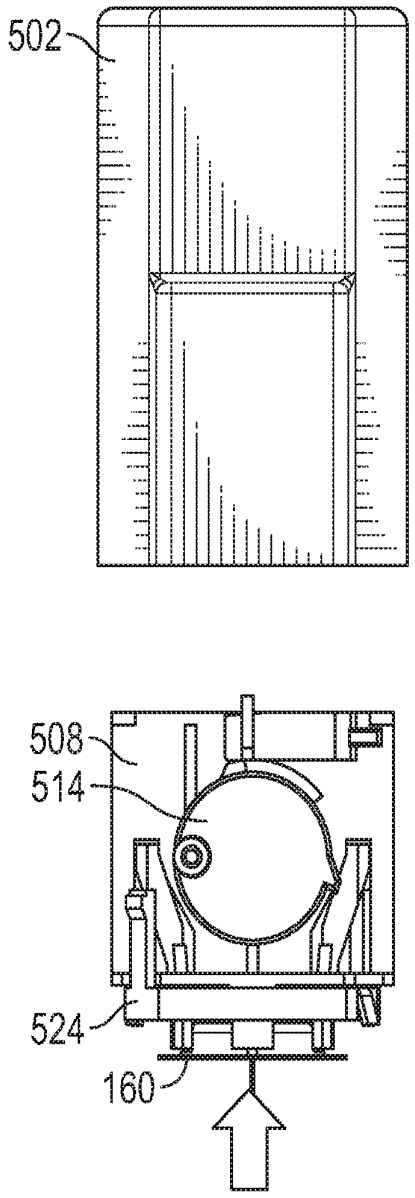


FIG. 11E

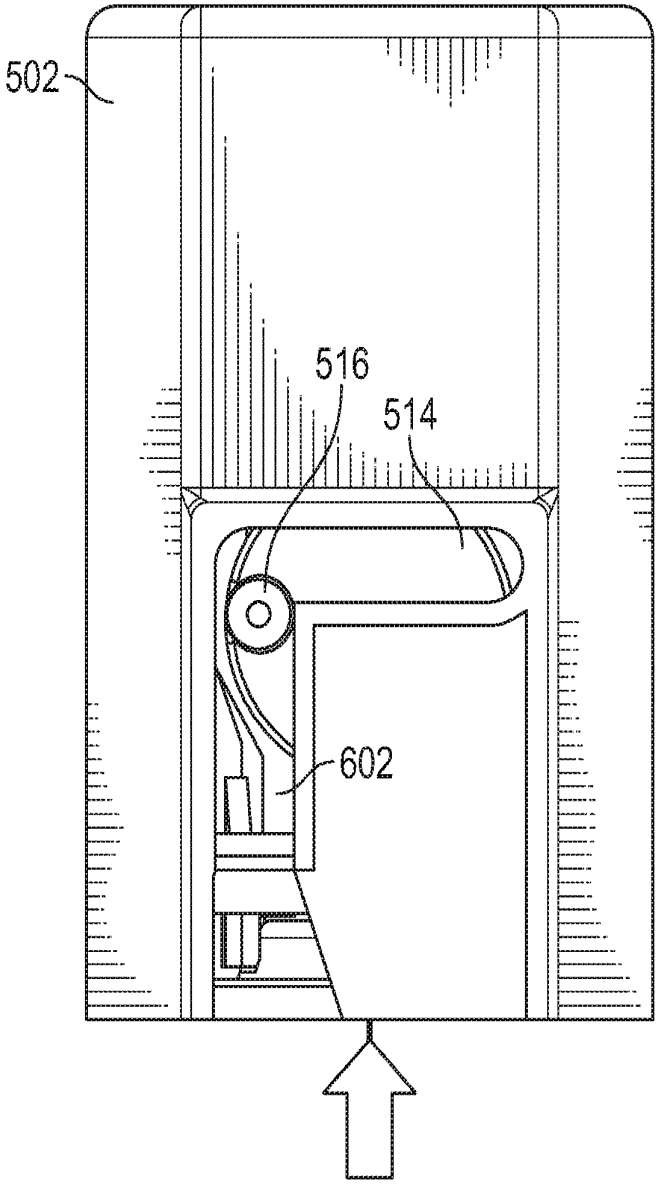


FIG. 11F

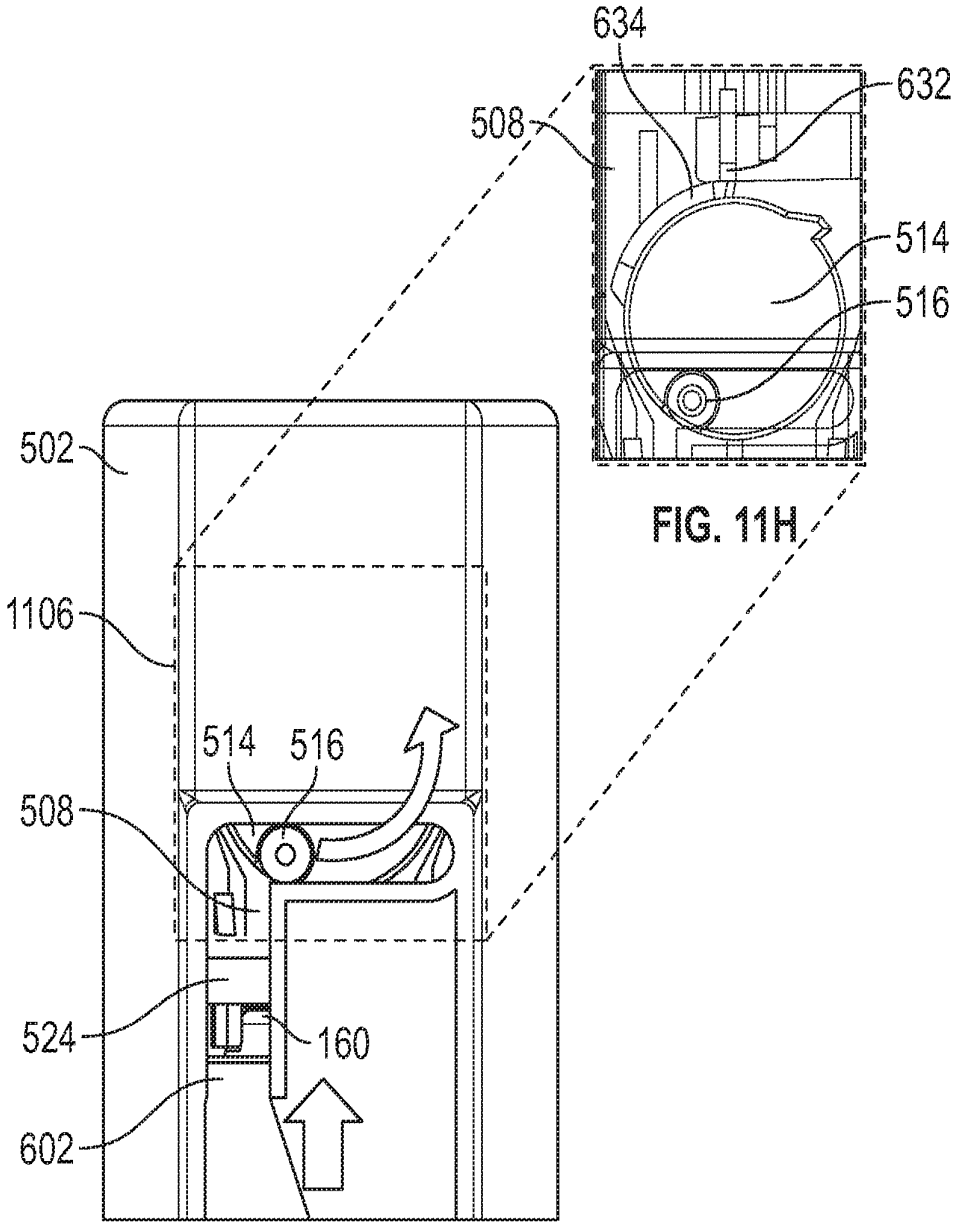


FIG. 11H

FIG. 11G

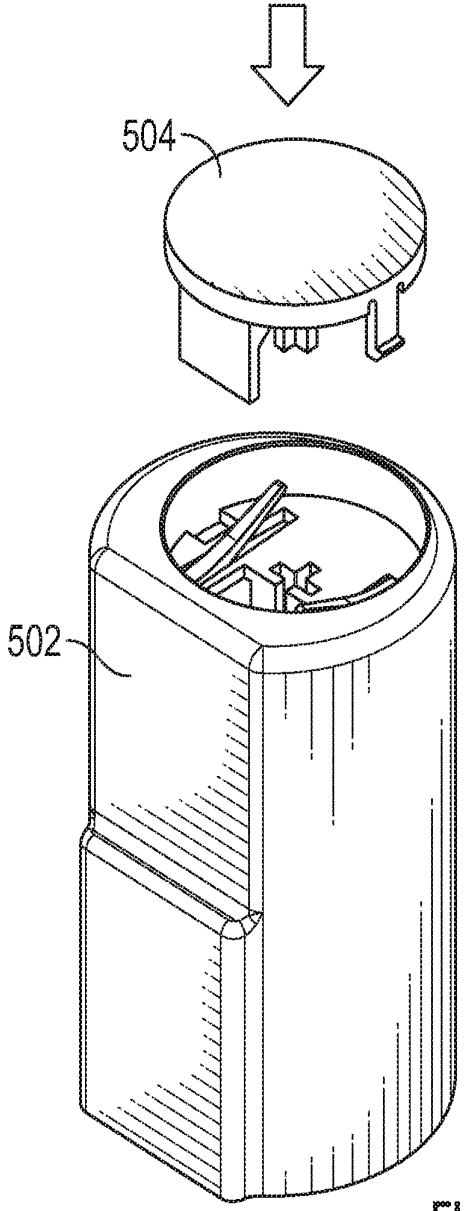


FIG. 11J

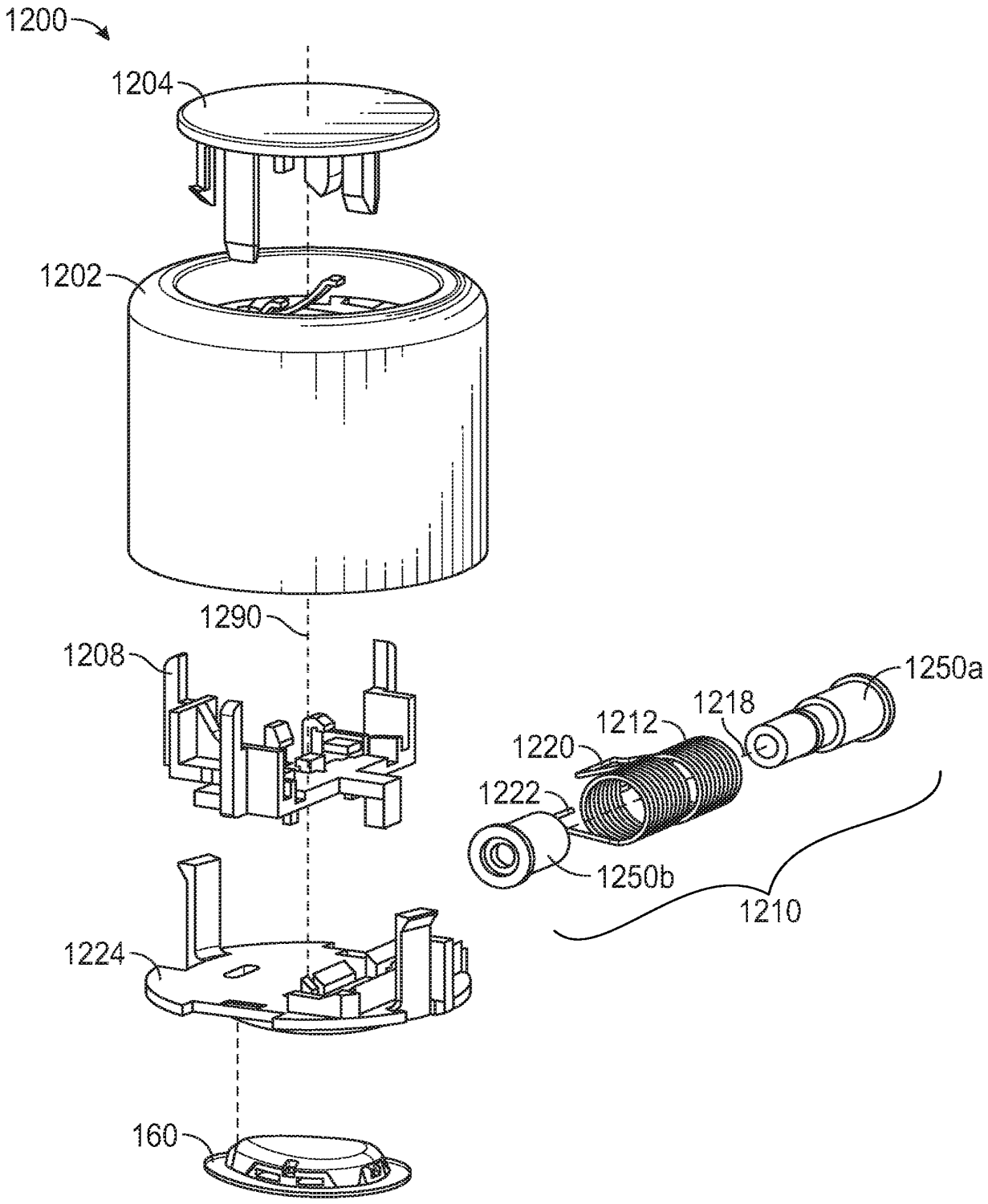

1200
1204
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1250a
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1220
1222
1250b
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1224
160

FIG. 12

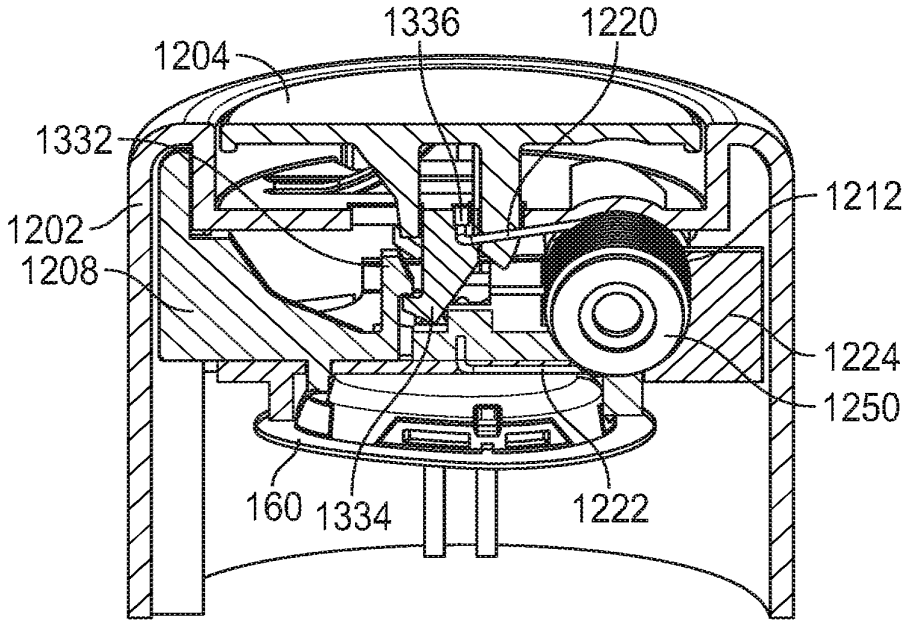


FIG. 13A

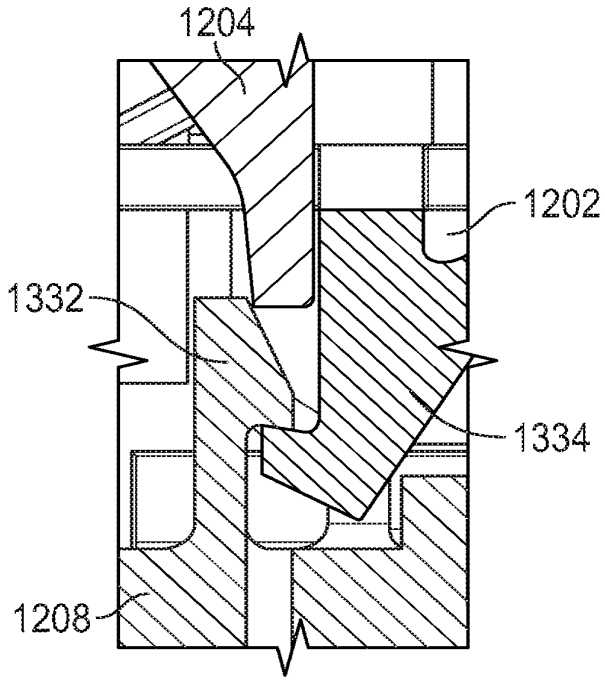


FIG. 13B

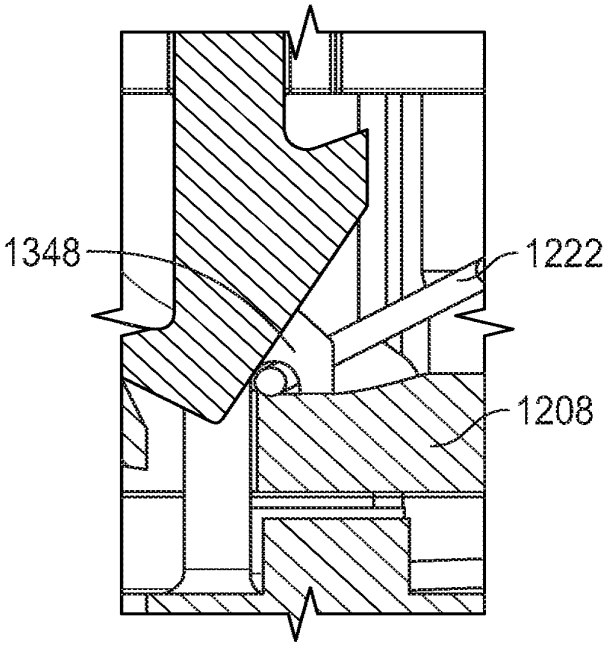


FIG. 13C

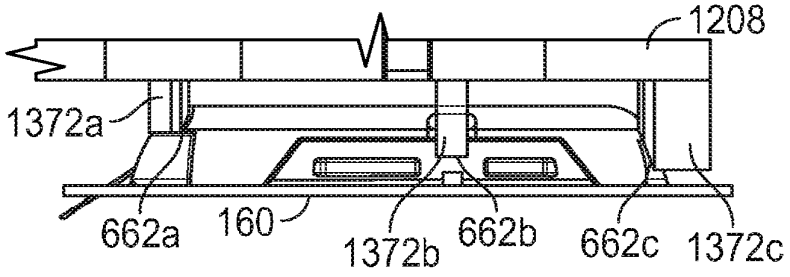


FIG. 13D

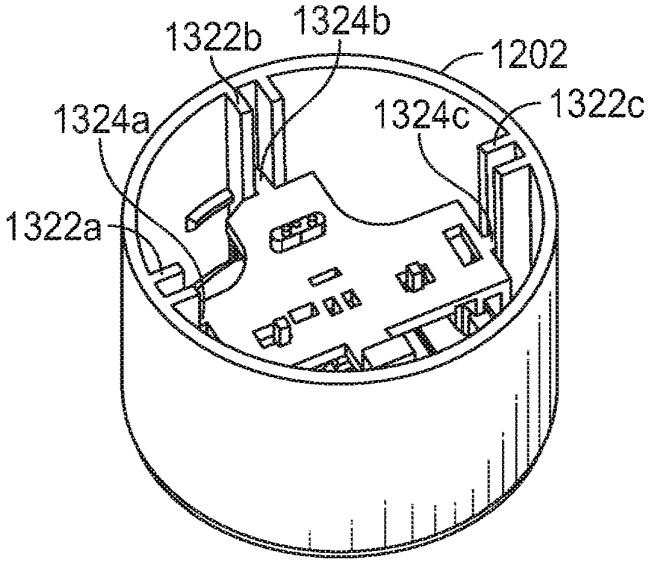


FIG. 13E

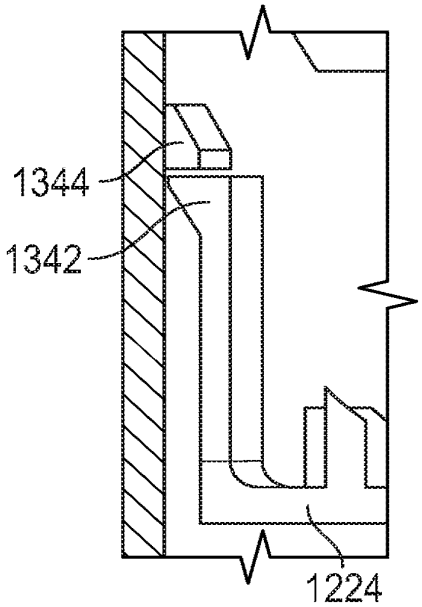


FIG. 13F

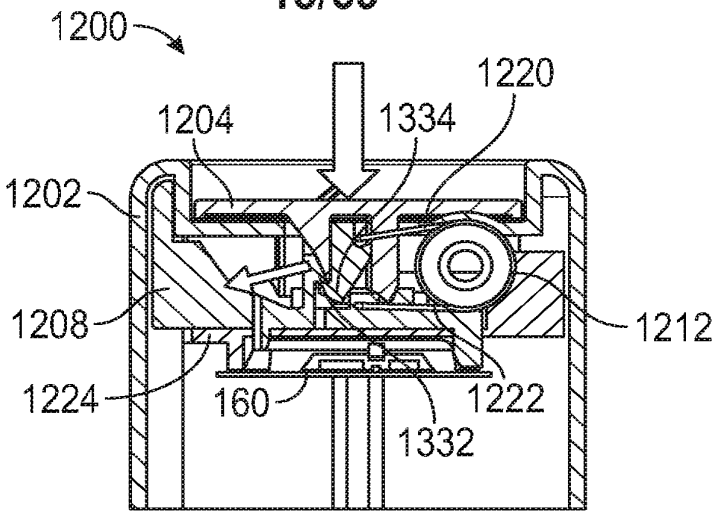


FIG. 14A

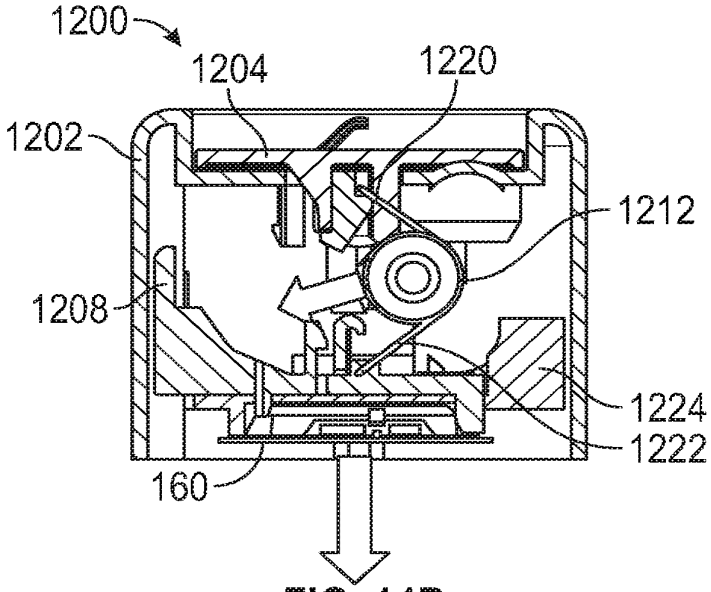


FIG. 14B

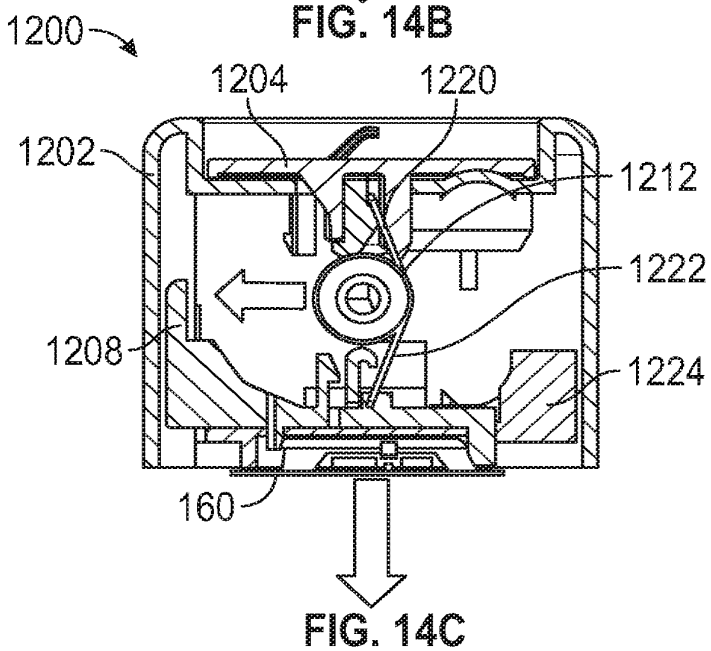


FIG. 14C

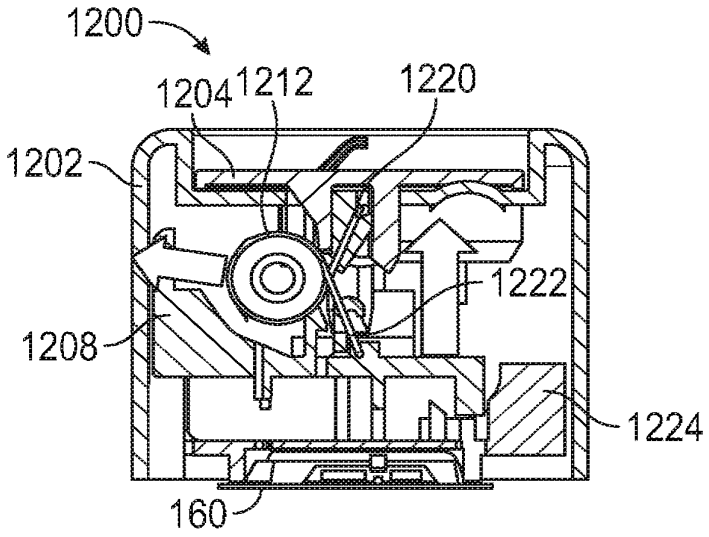


FIG. 14D

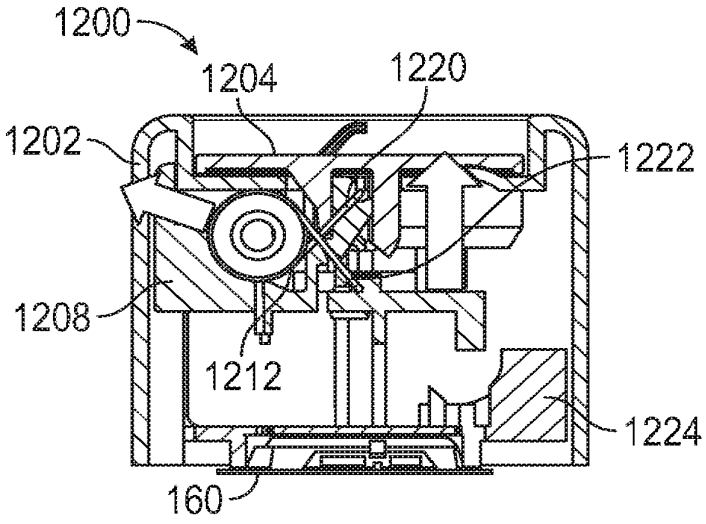


FIG. 14E

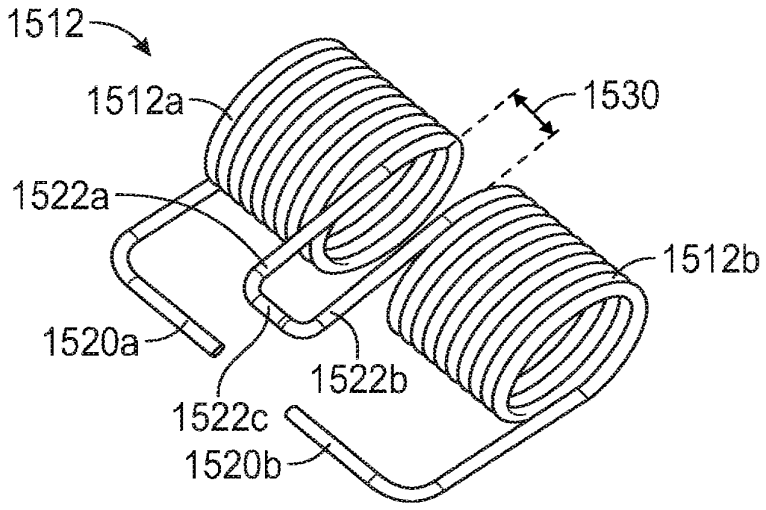


FIG. 15

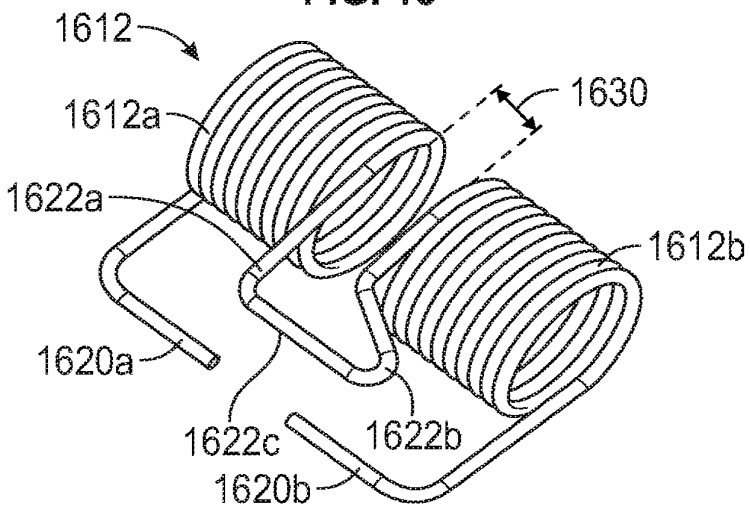


FIG. 16

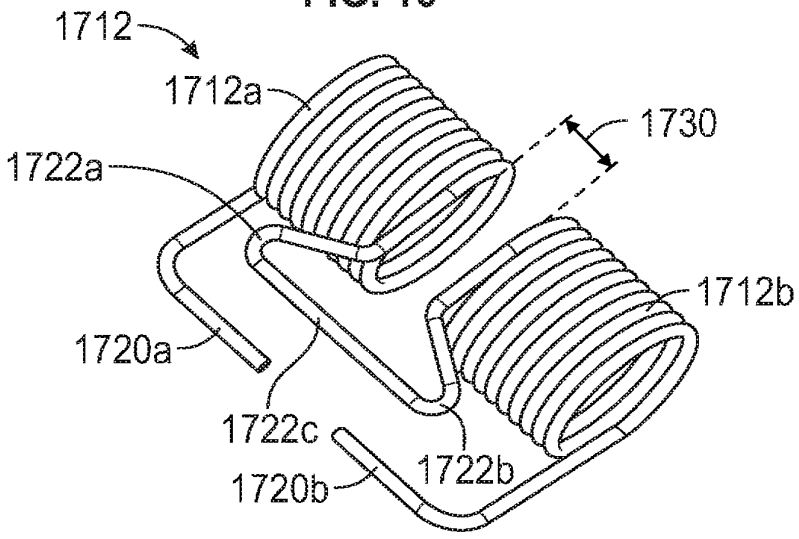


FIG. 17

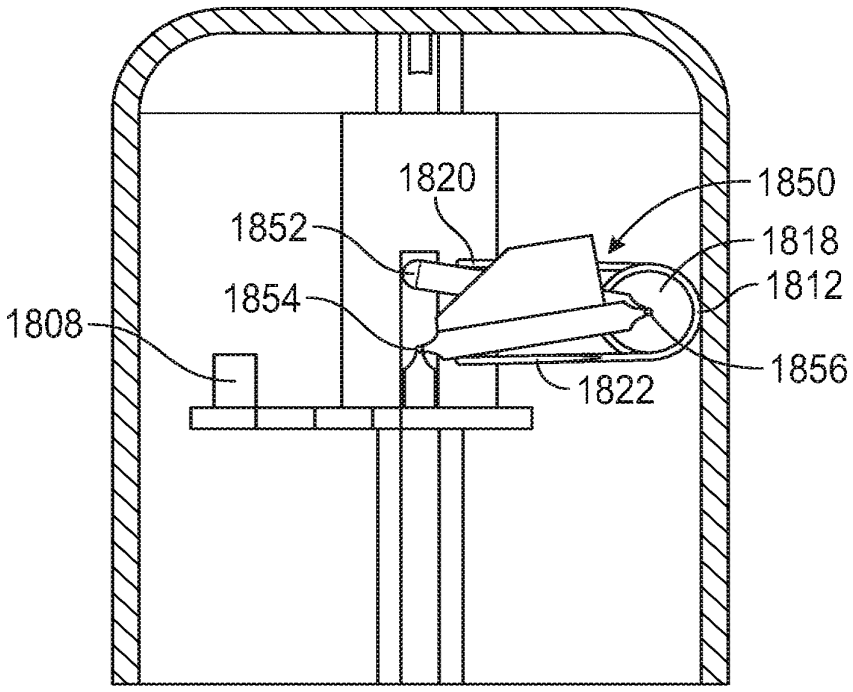

1820
1850
1852
1818
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1808
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1822

FIG. 18

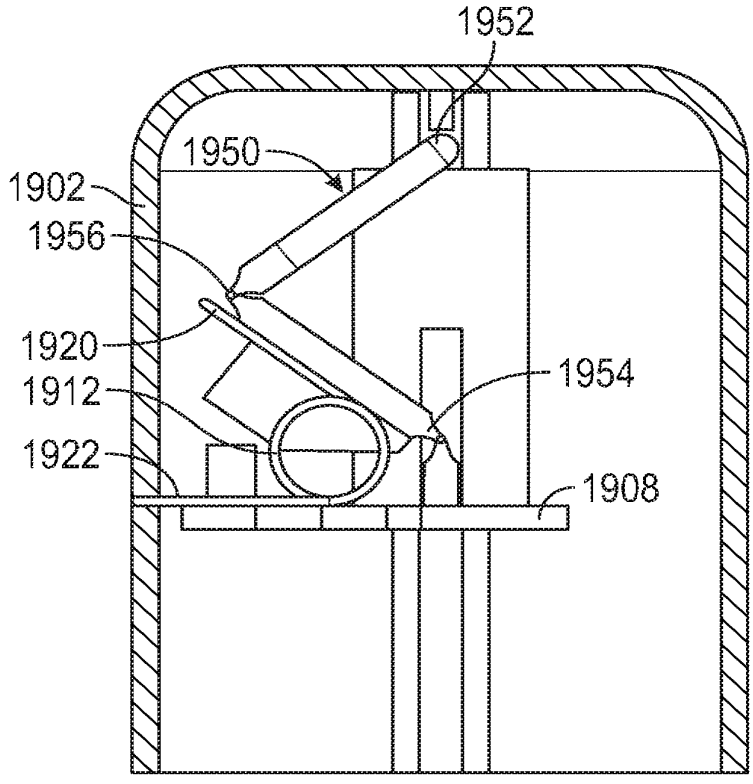

1952
1950
1902
1956
1920
1954
1912
1922
1908

FIG. 19

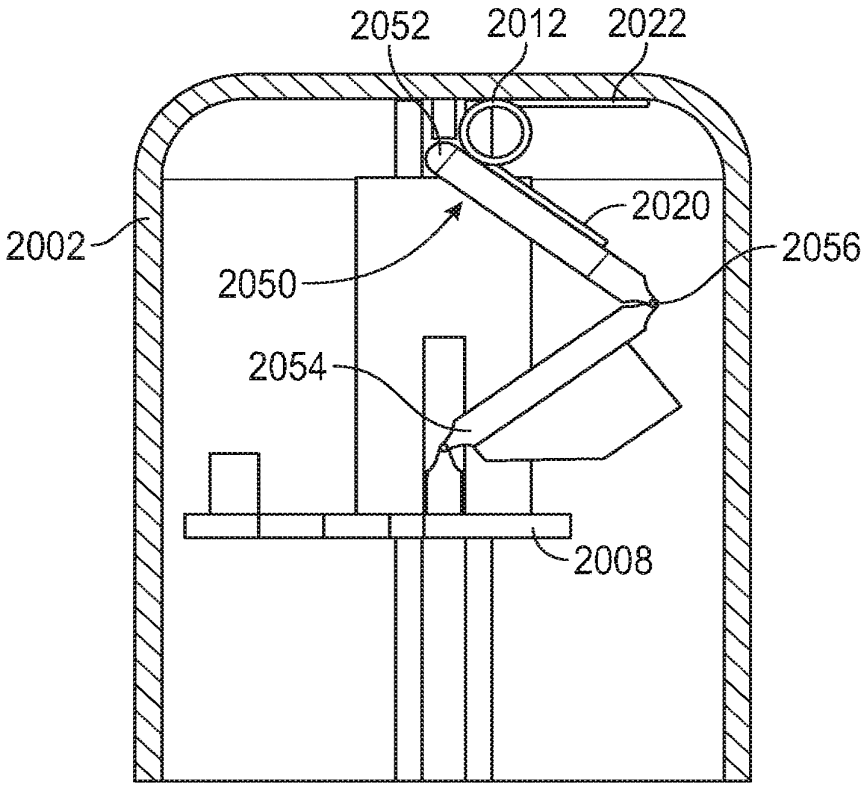

2052
2012
2022
2020
2002
2056
2050
2054
2008

FIG. 20

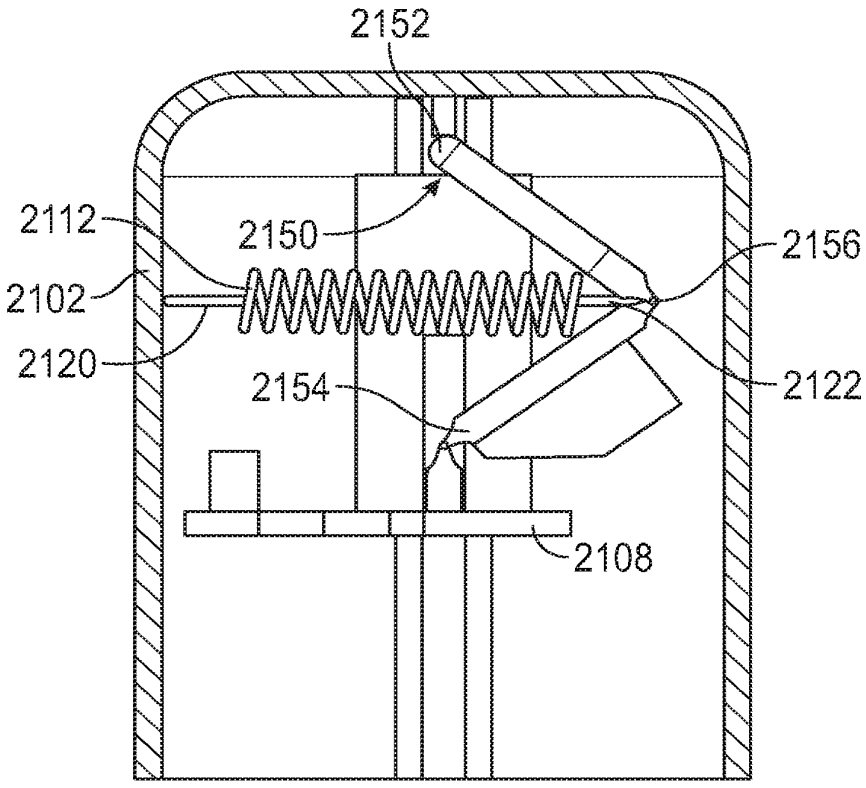

2152
2112
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2156
2102
2120
2122
2154
2108

FIG. 21

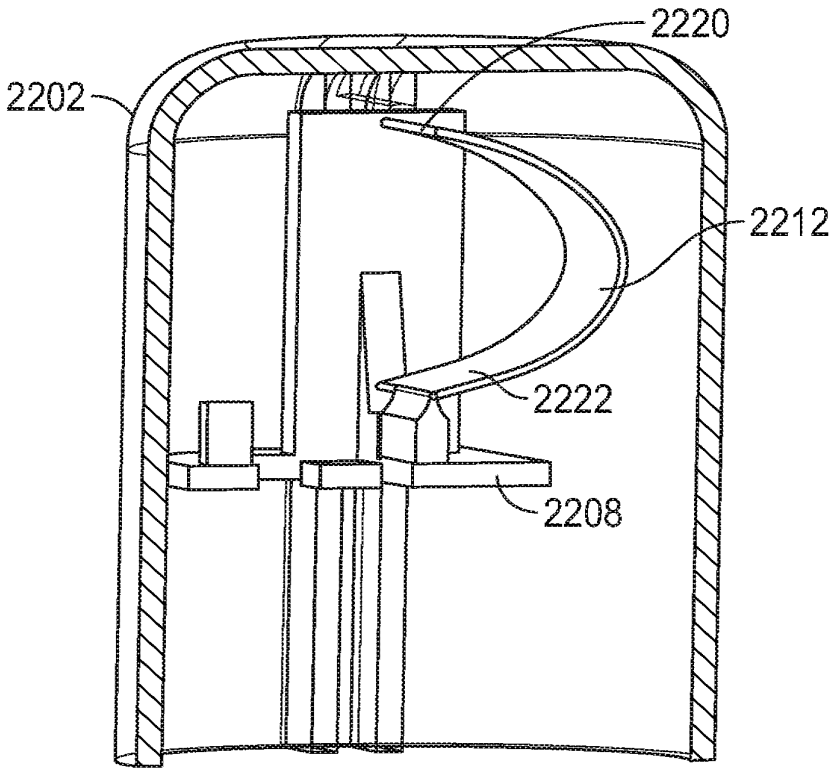

2220
2202
2212
2222
2208

FIG. 22

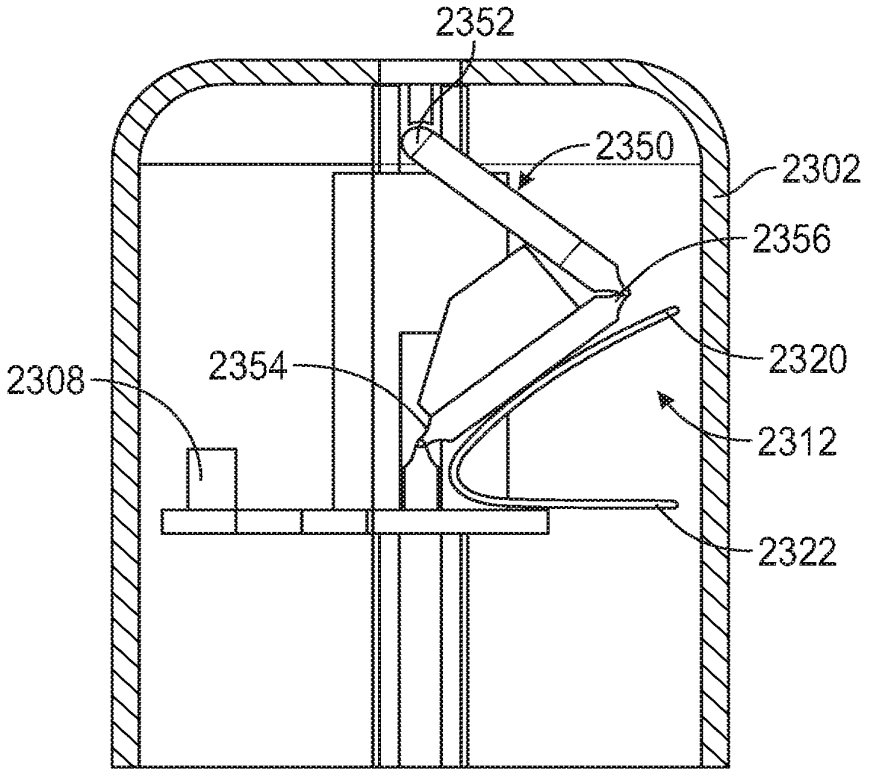

2352
2350
2302
2356
2320
2354
2308
2312
2322

FIG. 23

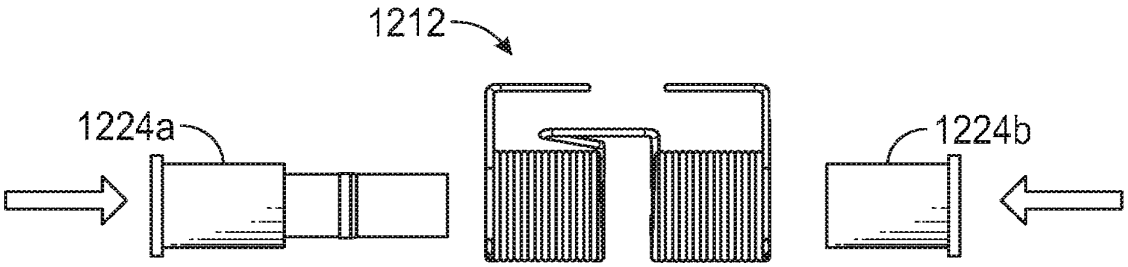


FIG. 24A

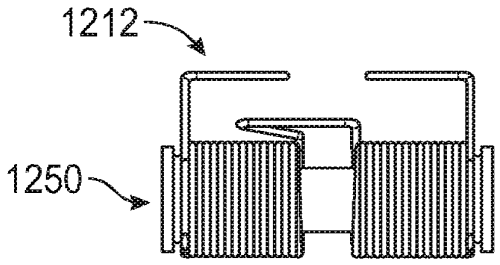


FIG. 24B

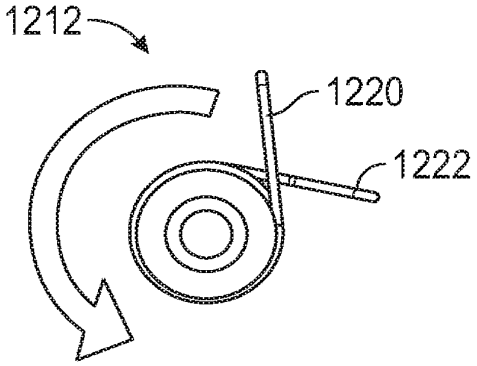


FIG. 24C

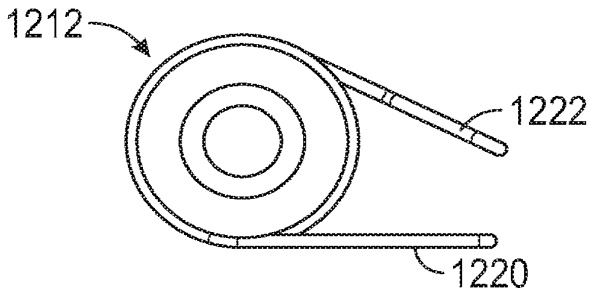


FIG. 24D

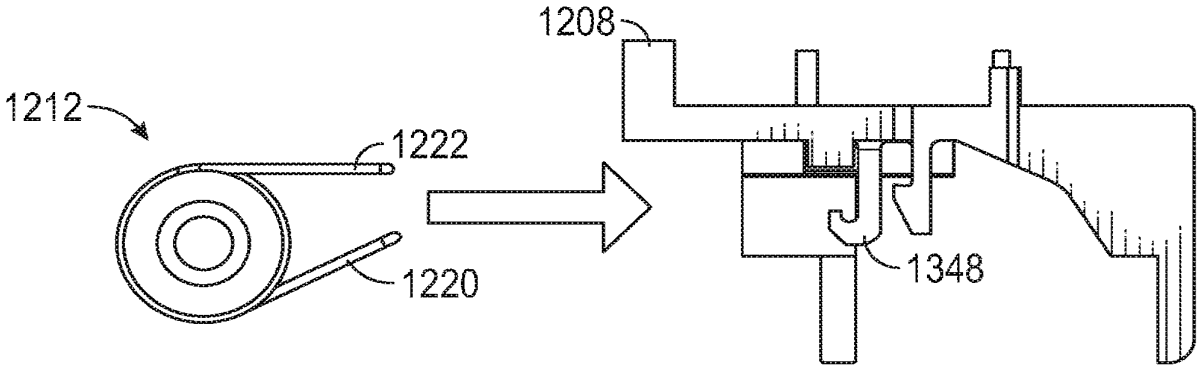


FIG. 24E

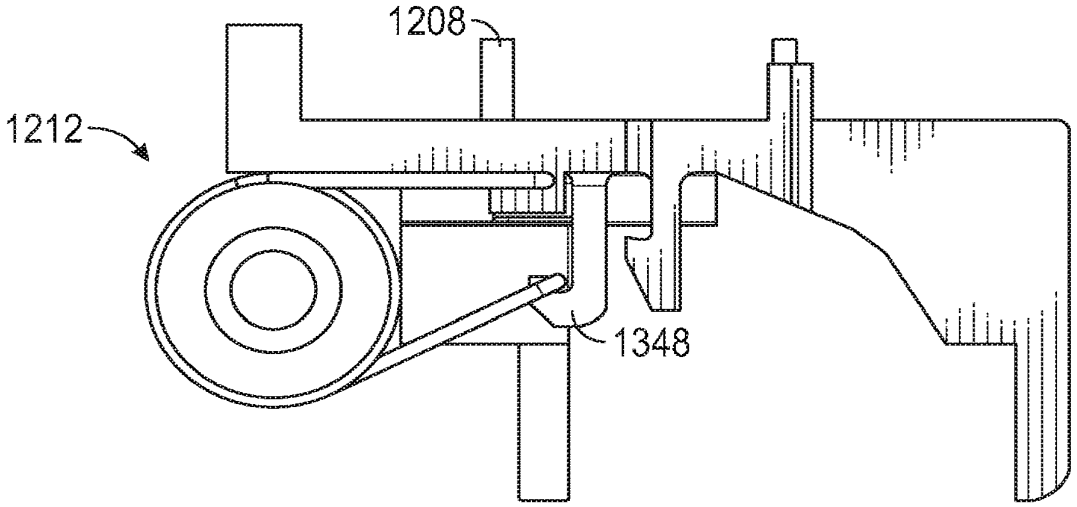


FIG. 24F

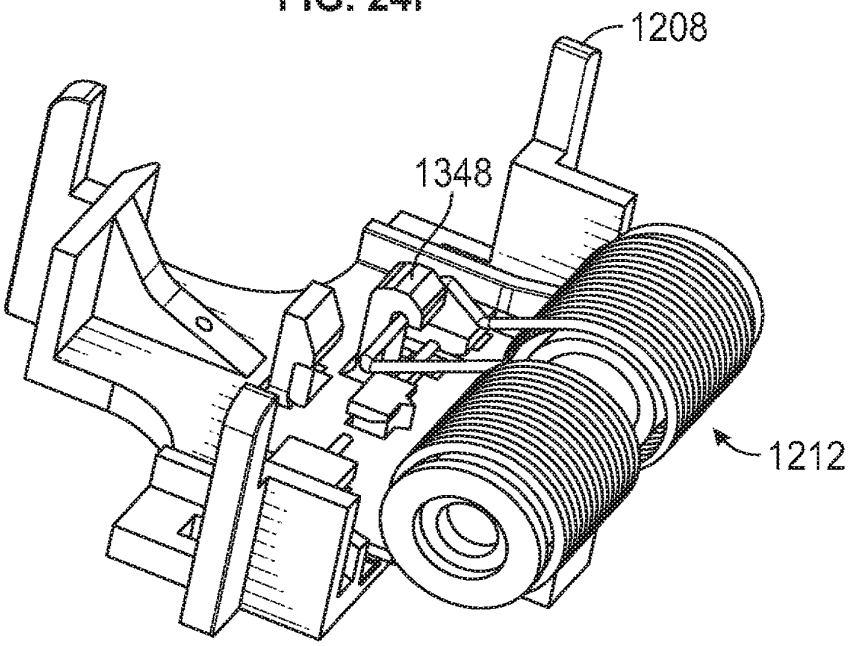


FIG. 24G

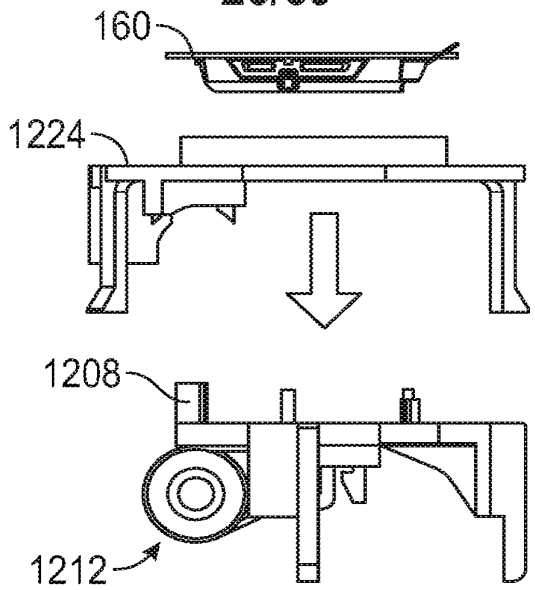


FIG. 24H

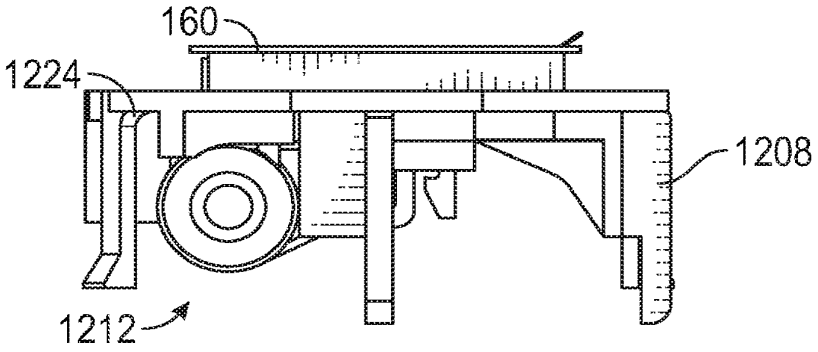


FIG. 24J

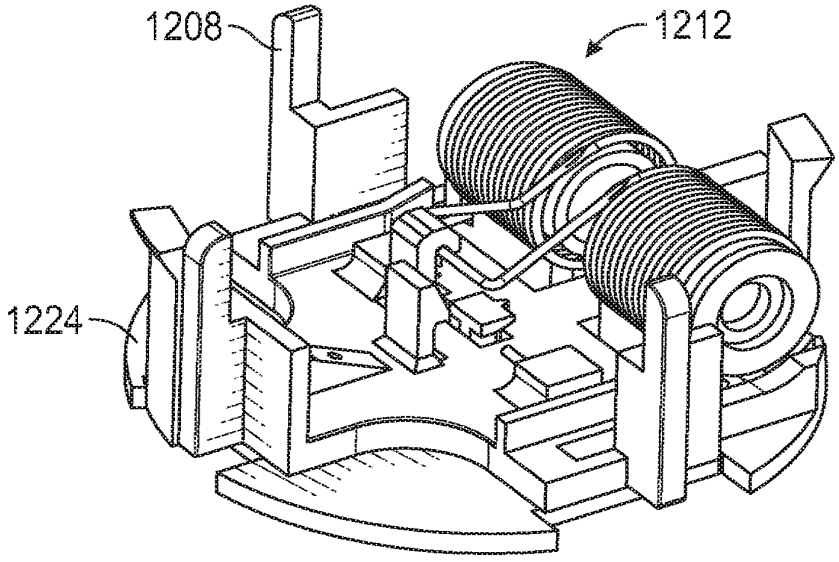


FIG. 24K

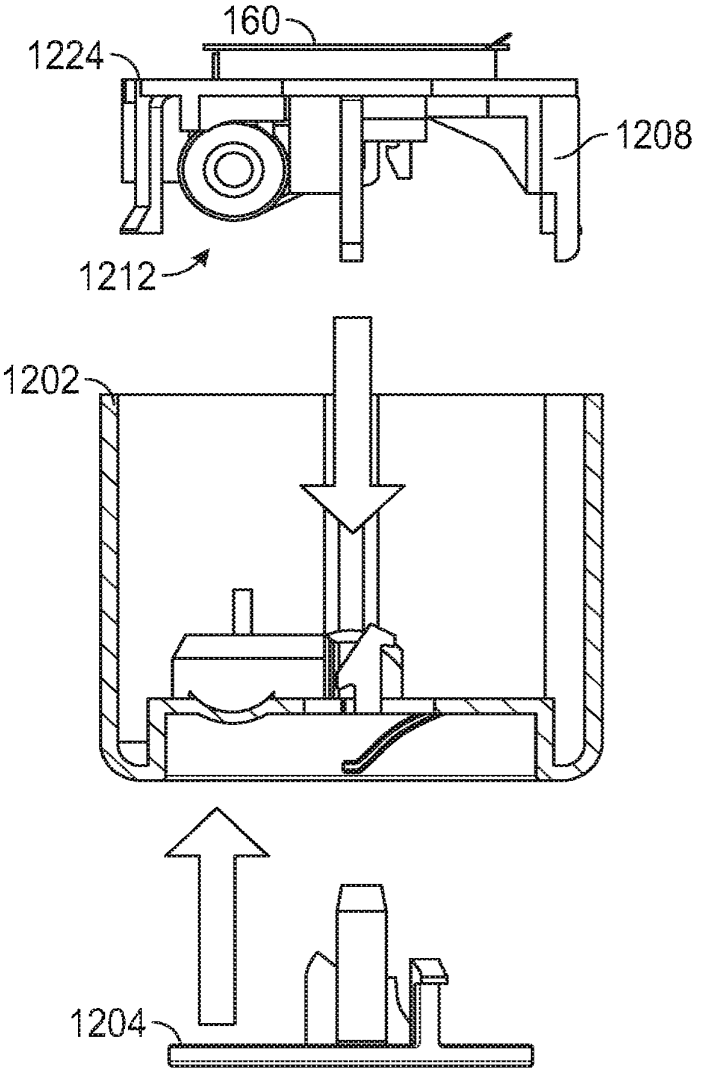


FIG. 24L

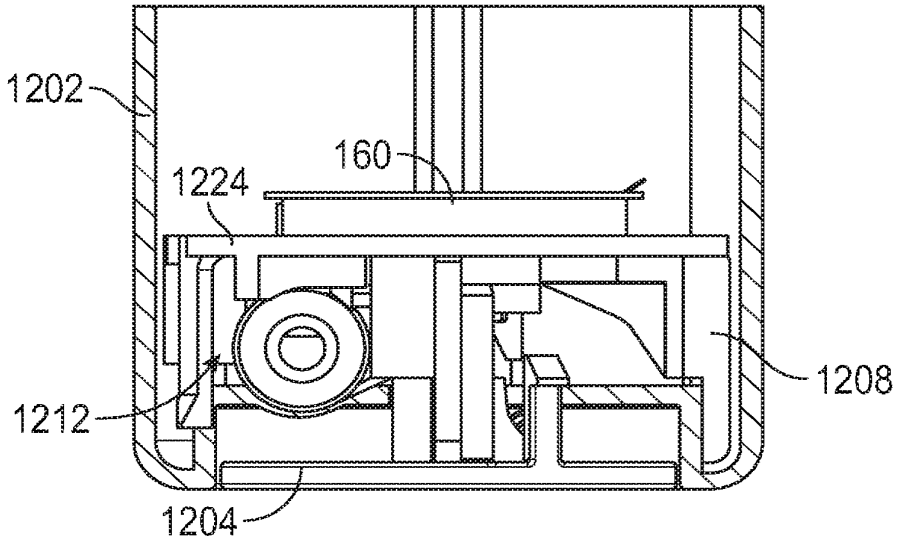


FIG. 24M

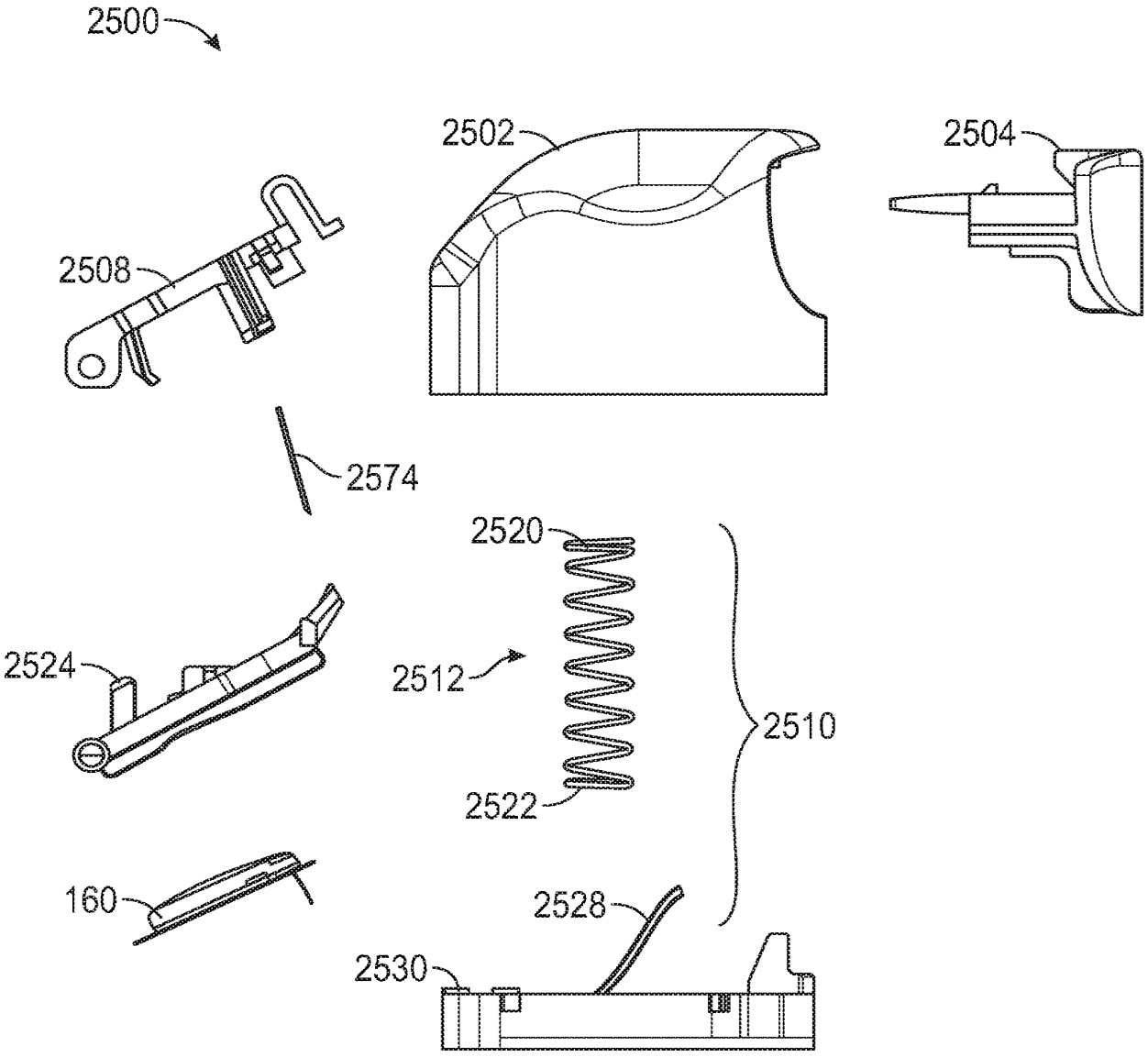

2500
2502
2504
2508
2574
2520
2524
2512
2510
2522
160
2528
2530

FIG. 25

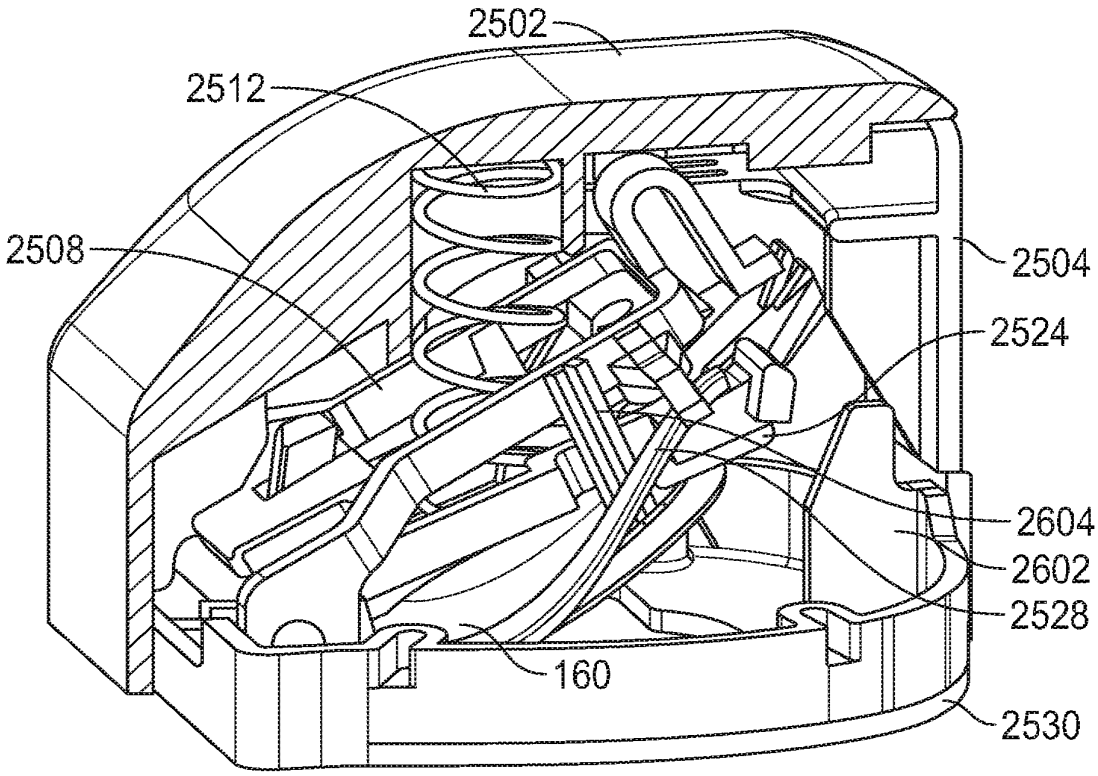


FIG. 26A

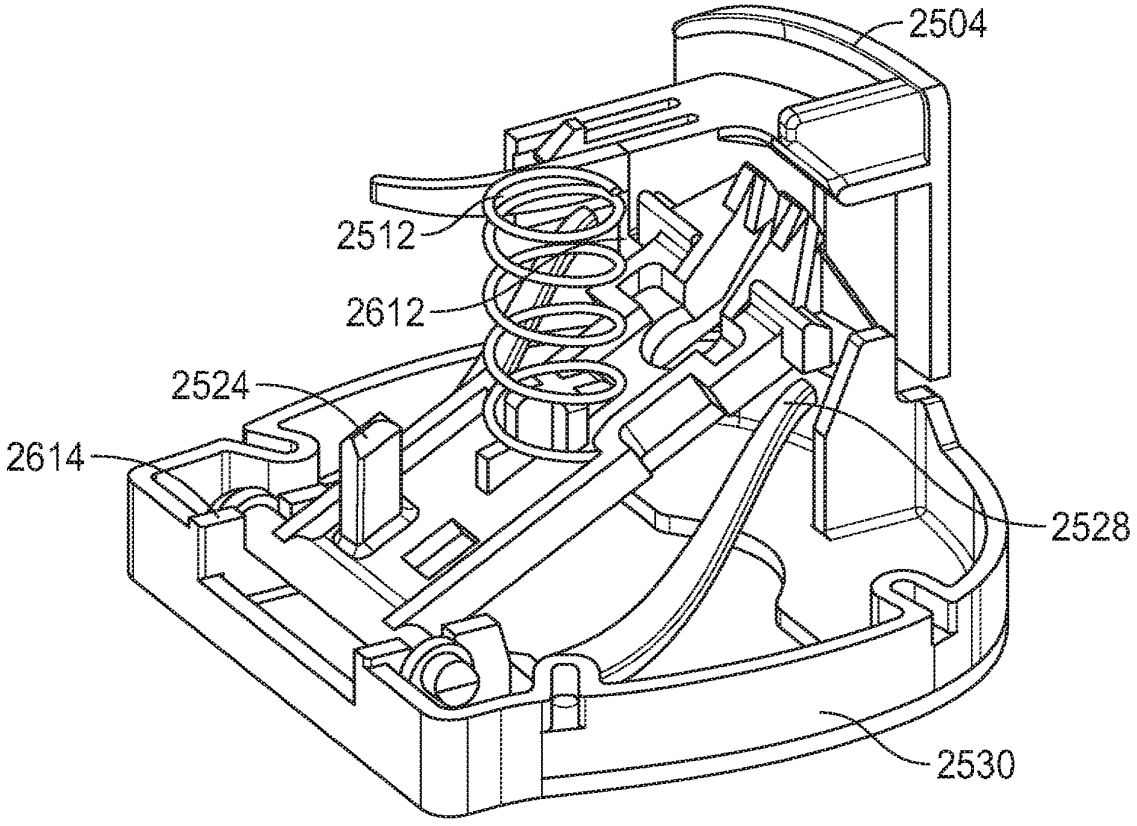


FIG. 26B

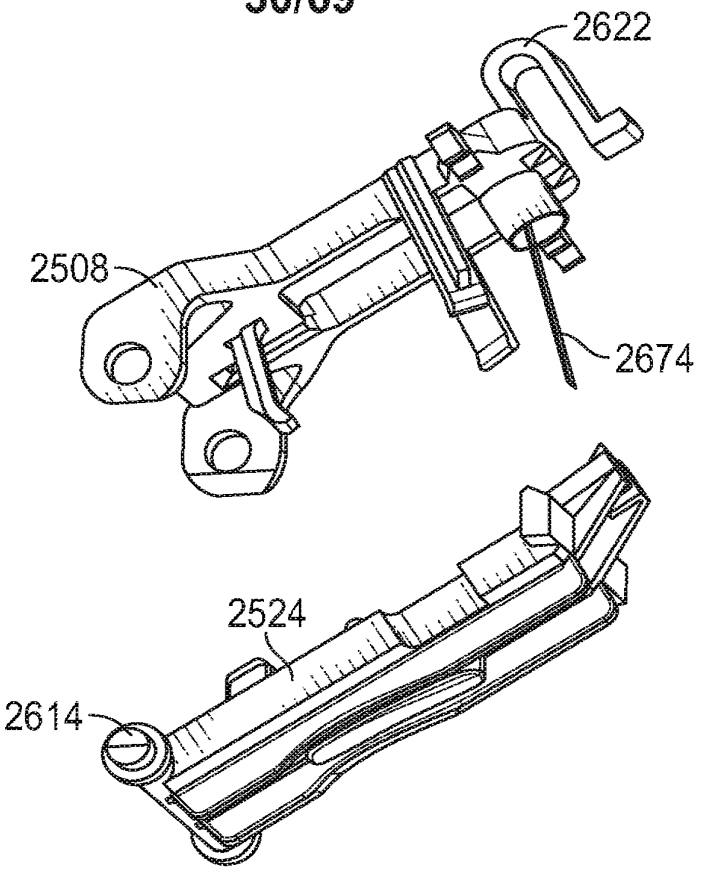


FIG. 26C

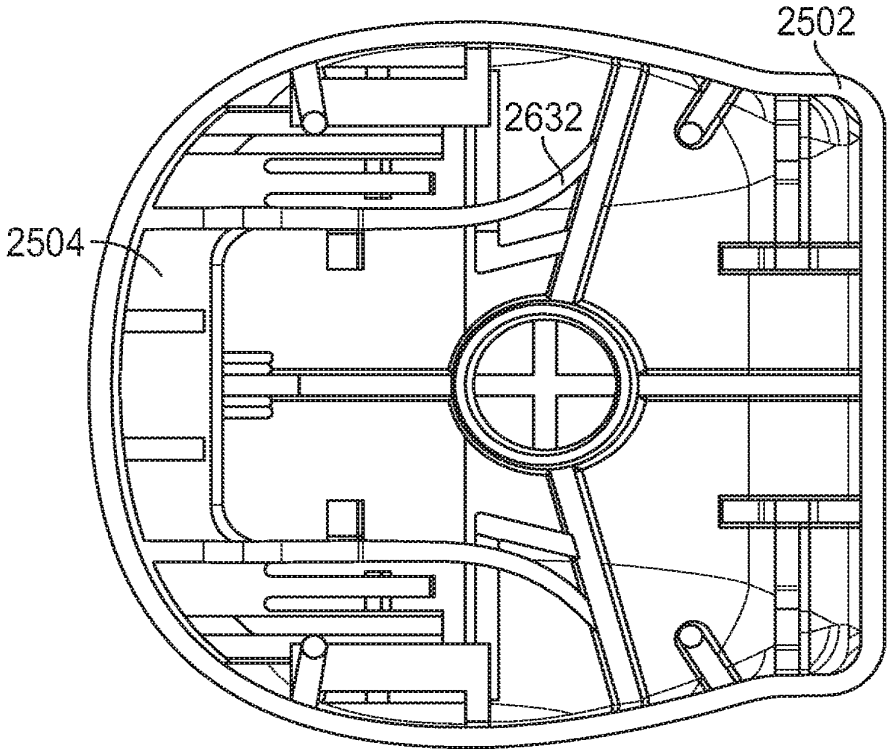


FIG. 26D

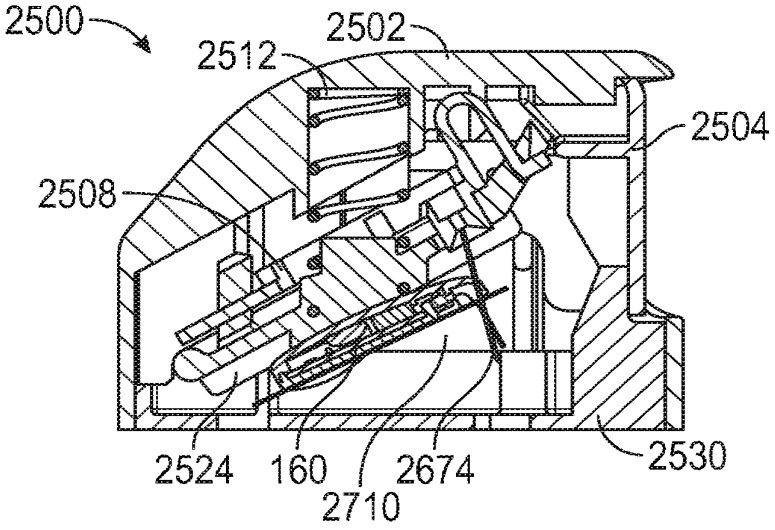


FIG. 27A

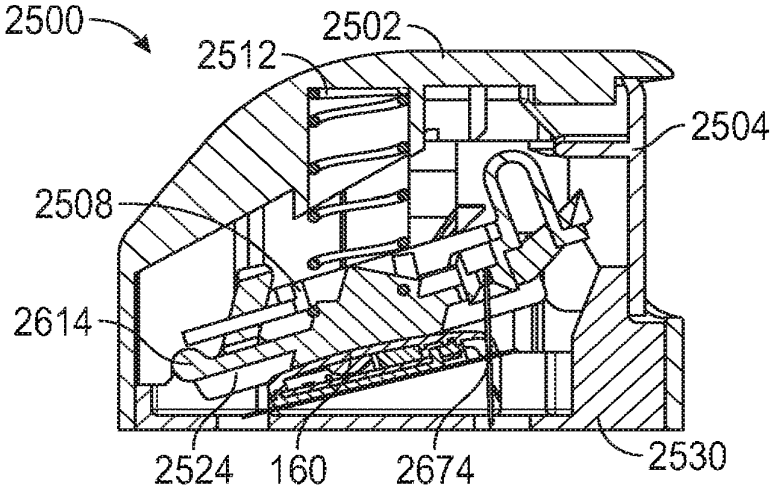


FIG. 27B

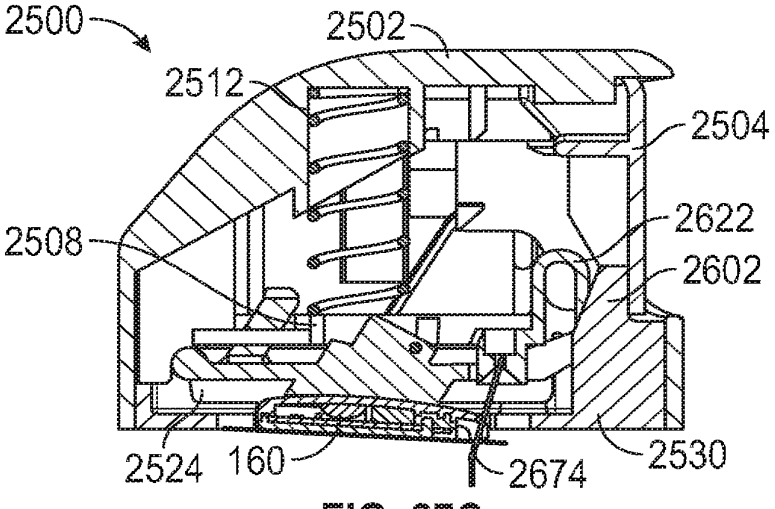


FIG. 27C

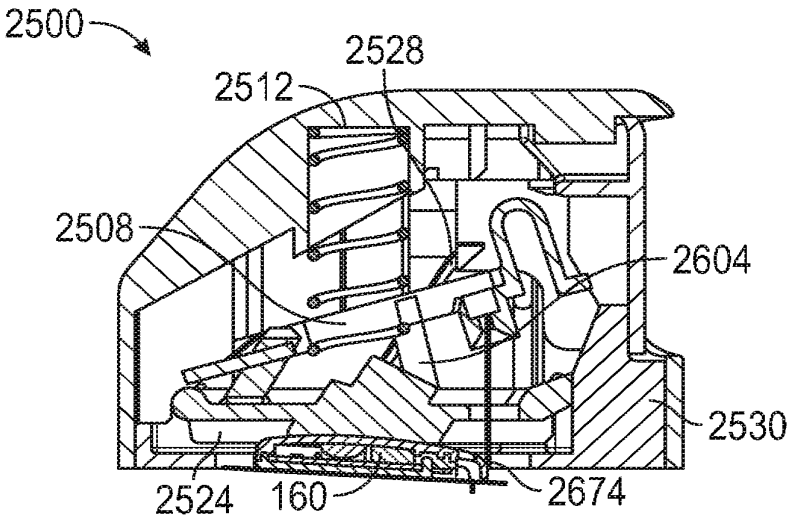


FIG. 27D

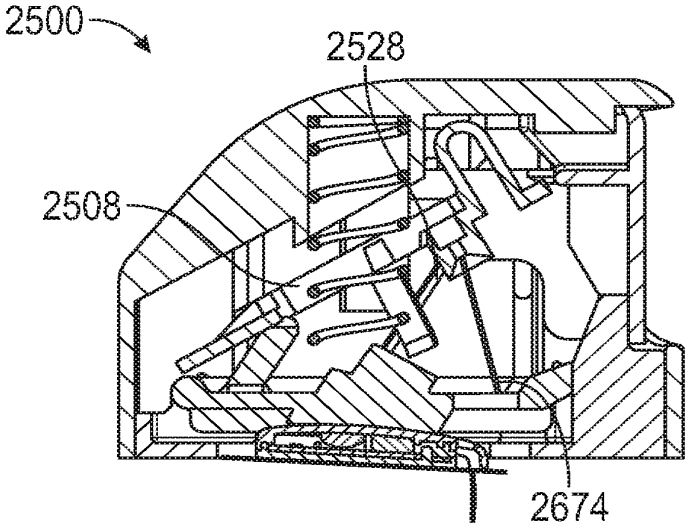


FIG. 27E

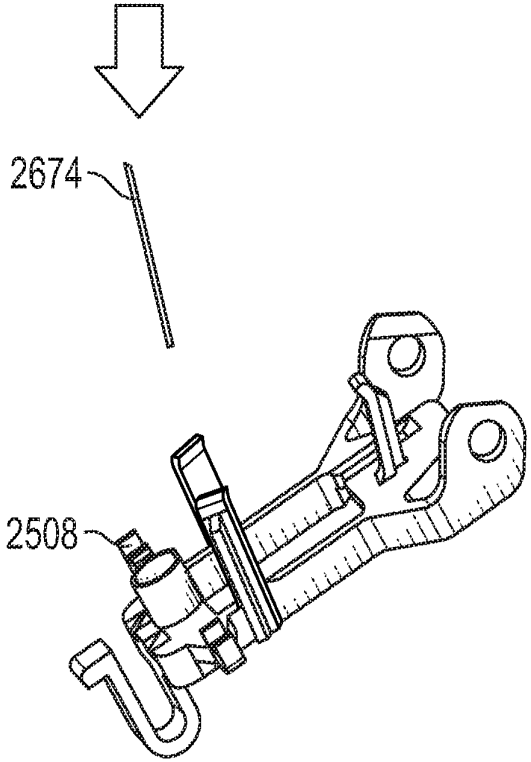


FIG. 28A

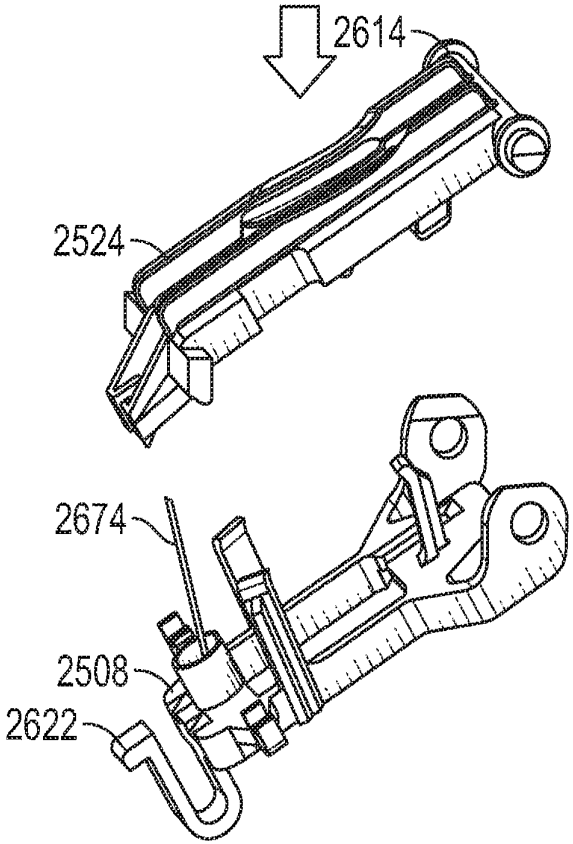


FIG. 28B

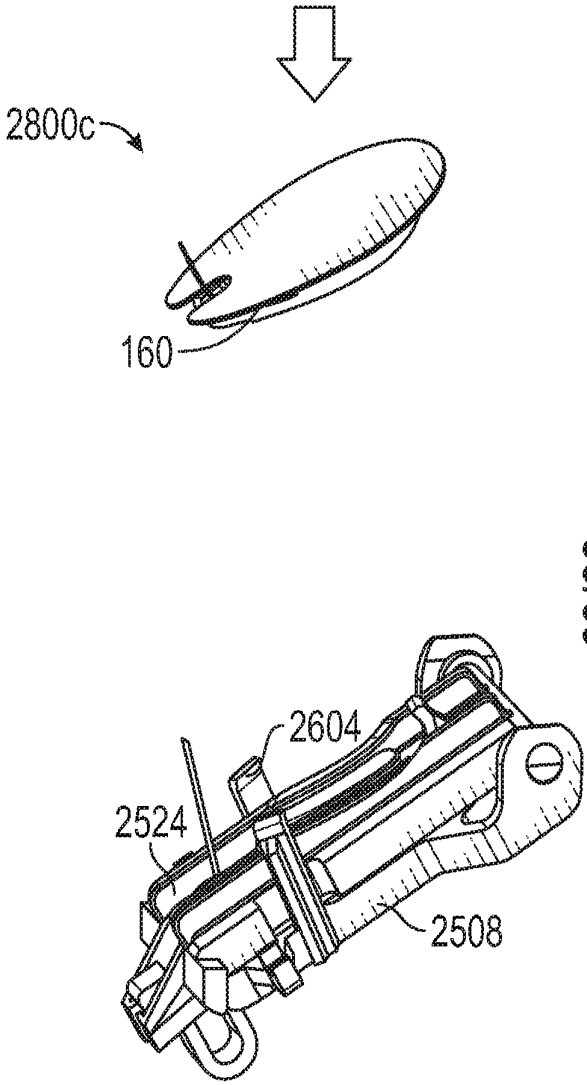


FIG. 28C

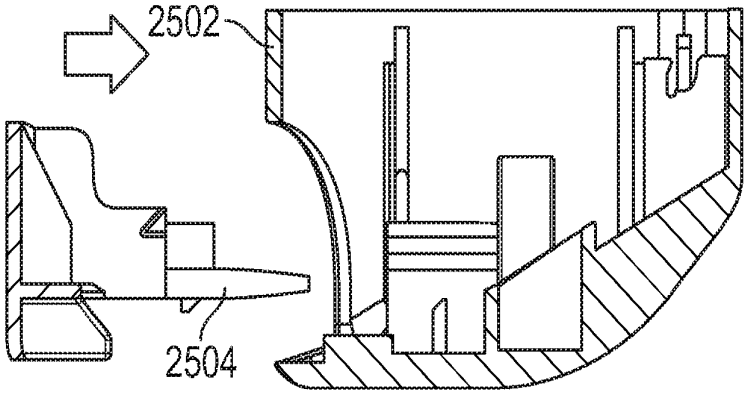
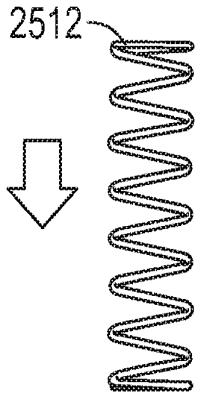
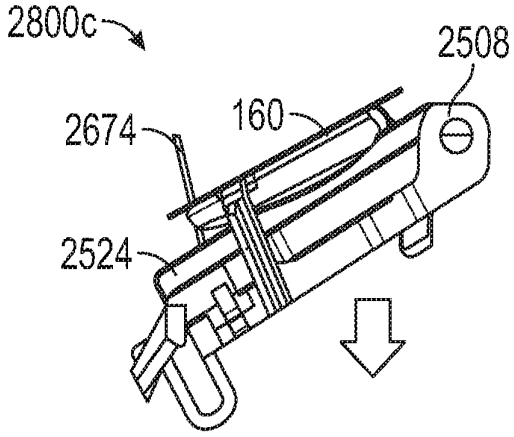


FIG. 28D





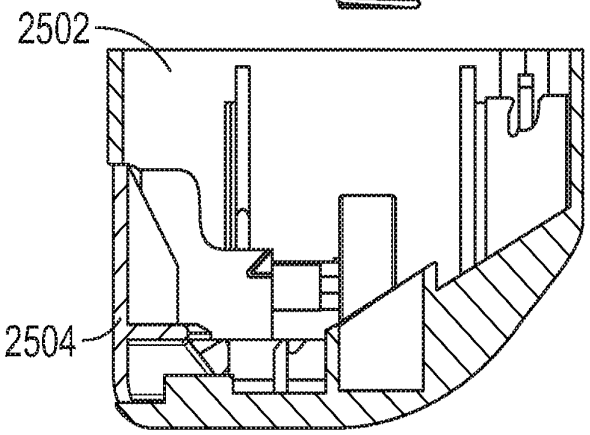


FIG. 28E

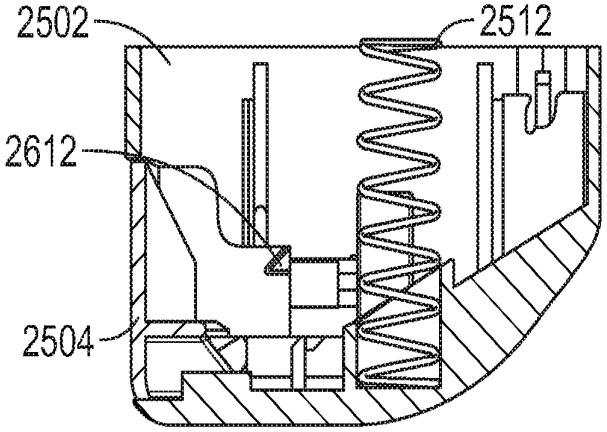


FIG. 28F

Abbott Ex. 1003 - 65/532

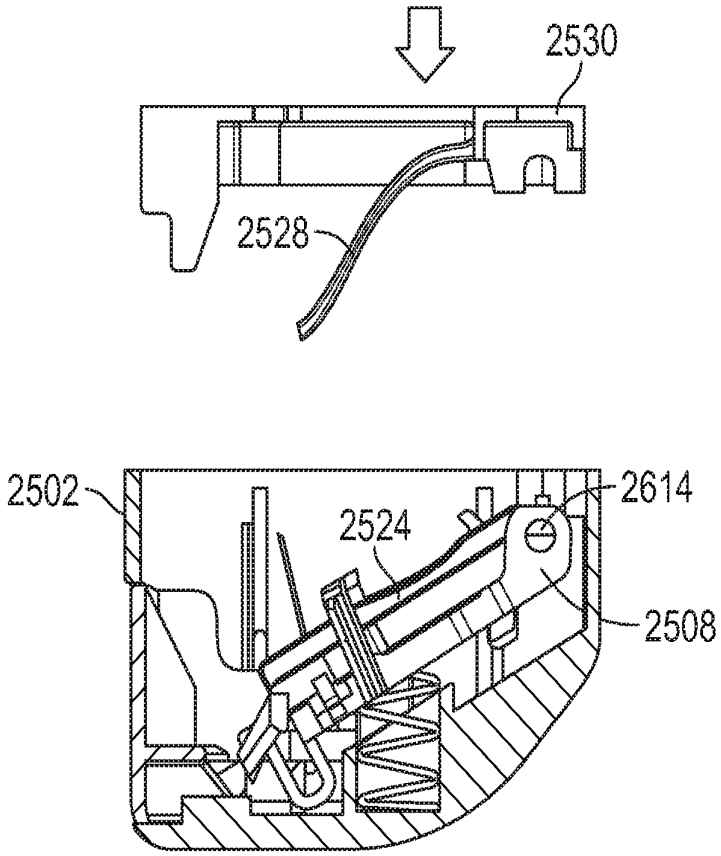


FIG. 28G

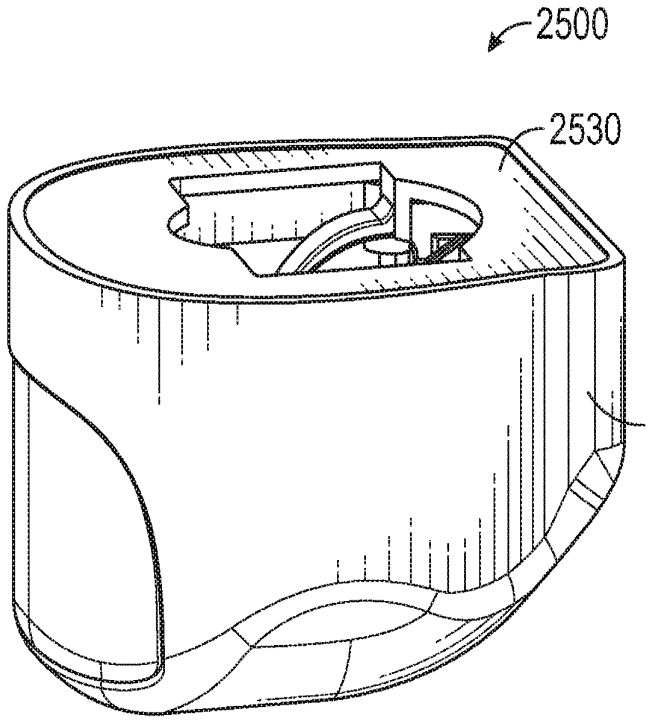


FIG. 28H

Abbott Ex. 1003 - 66/532

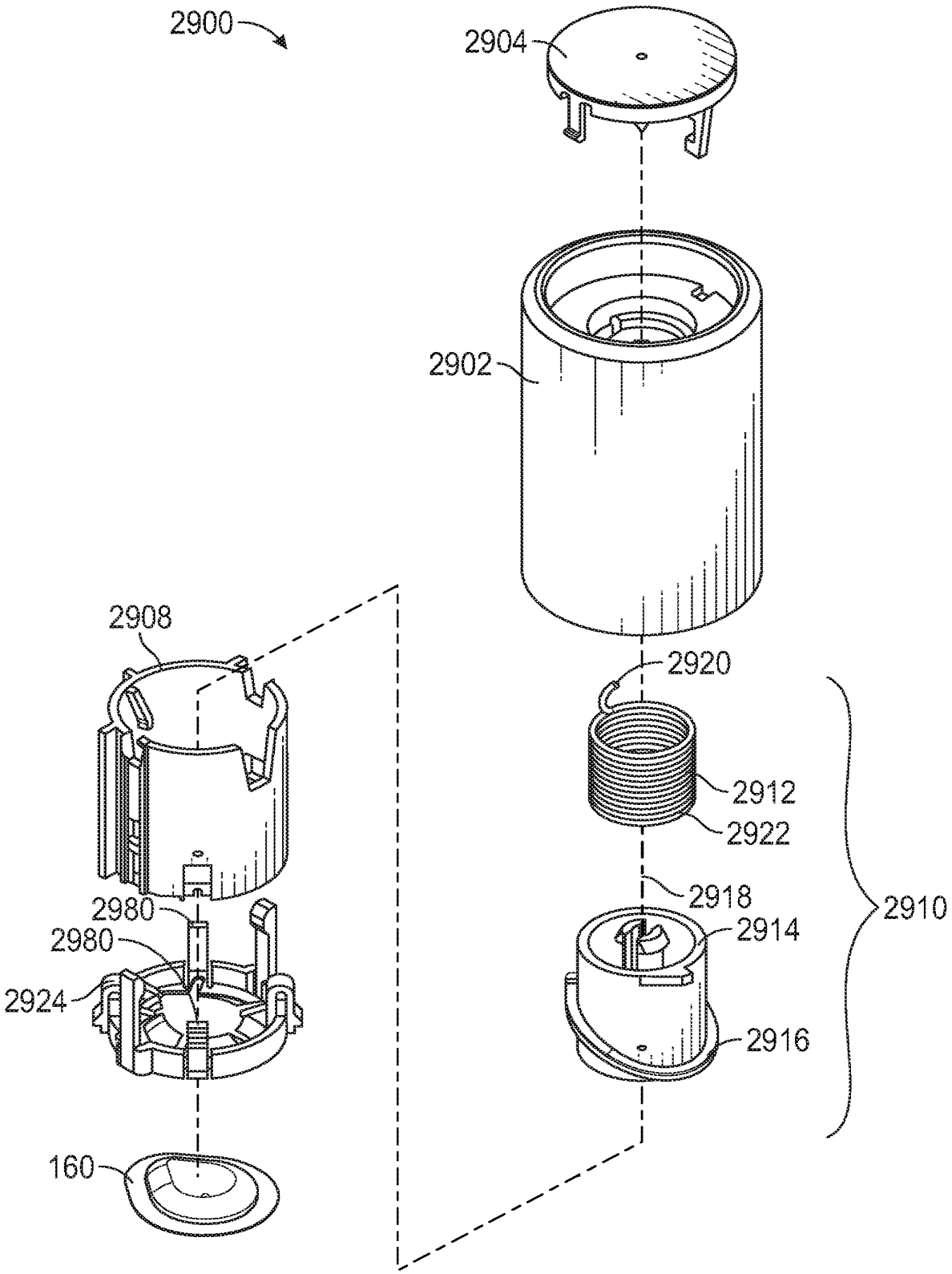

2900
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160

FIG. 29

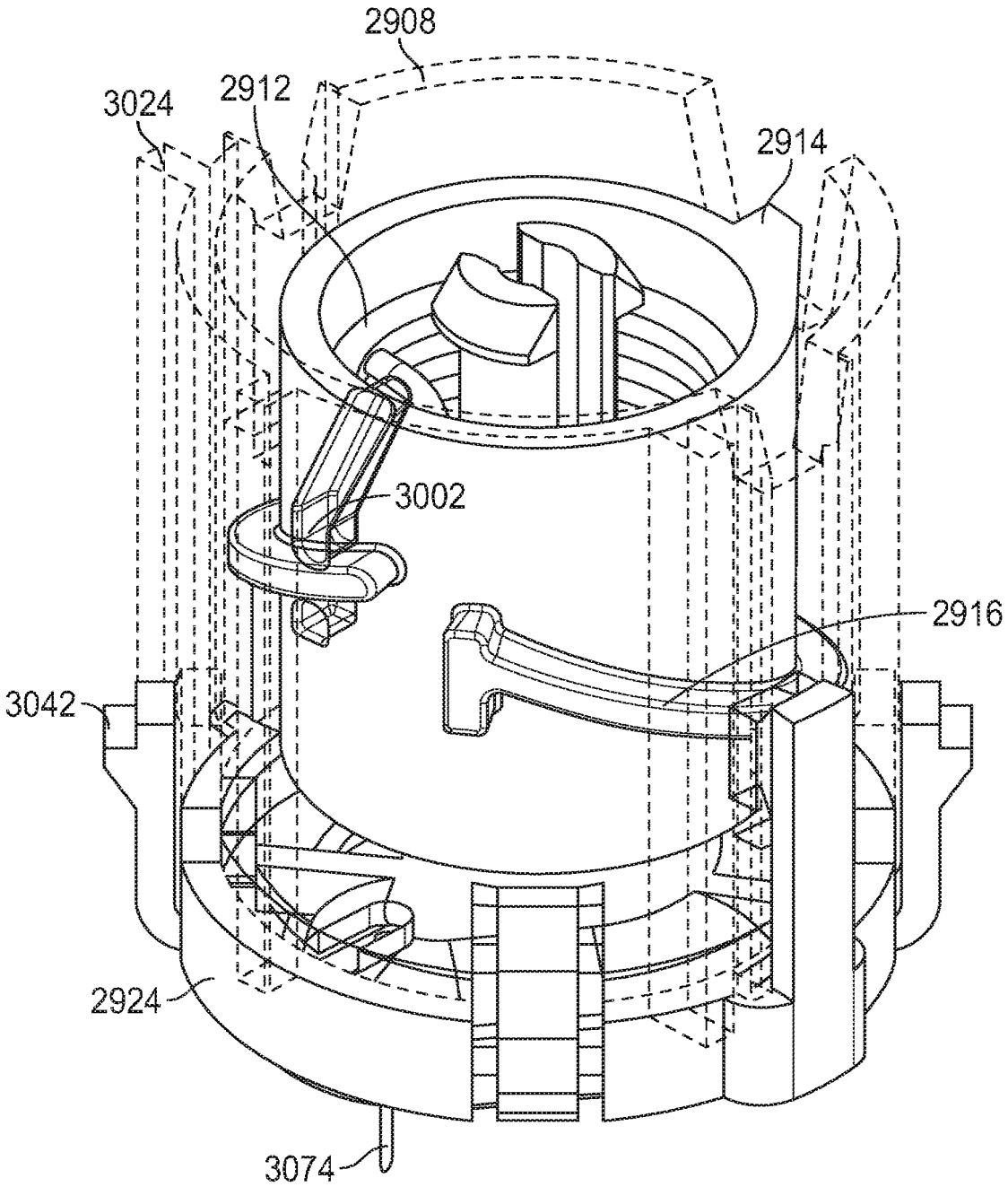


FIG. 30

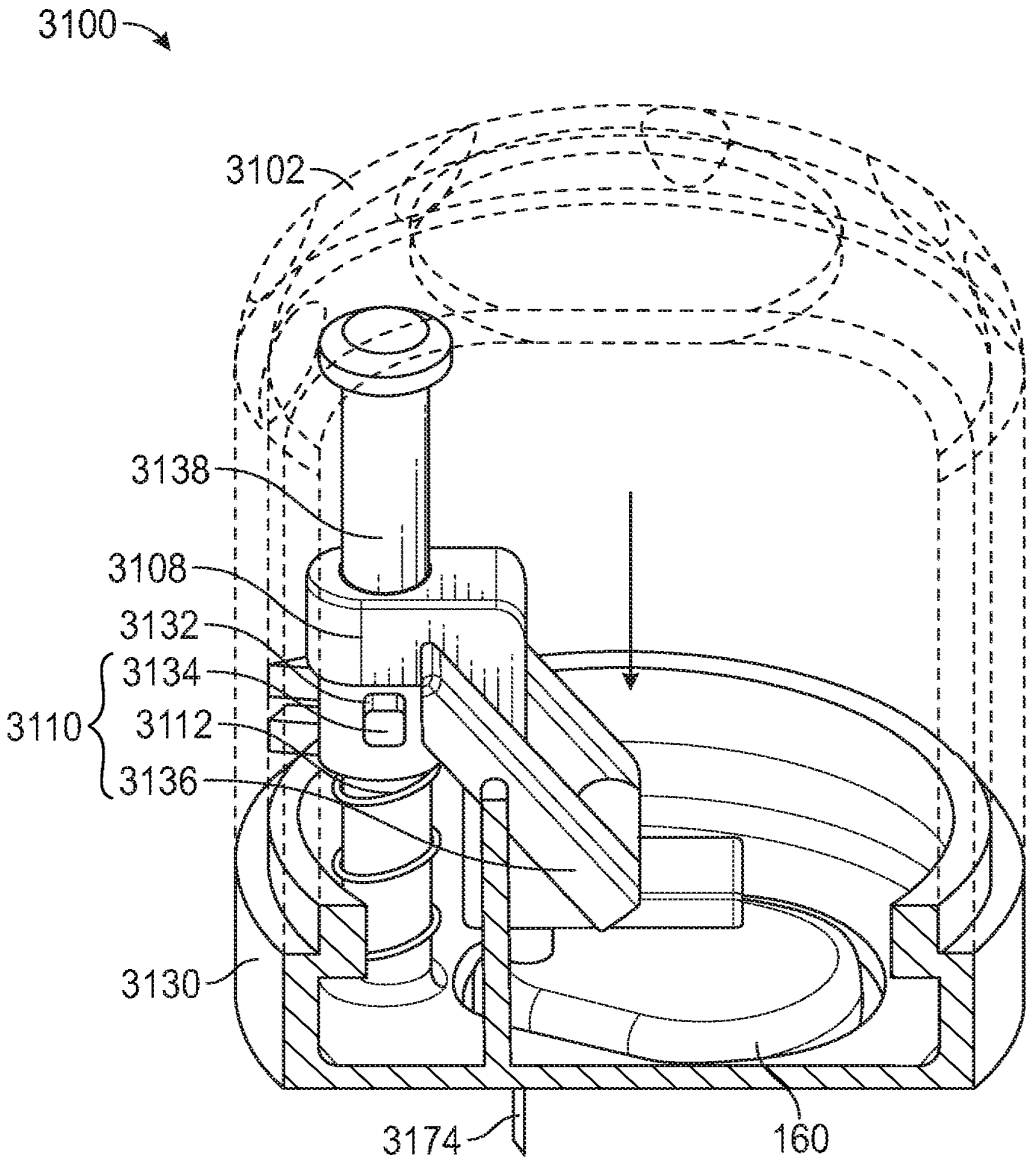


FIG. 31

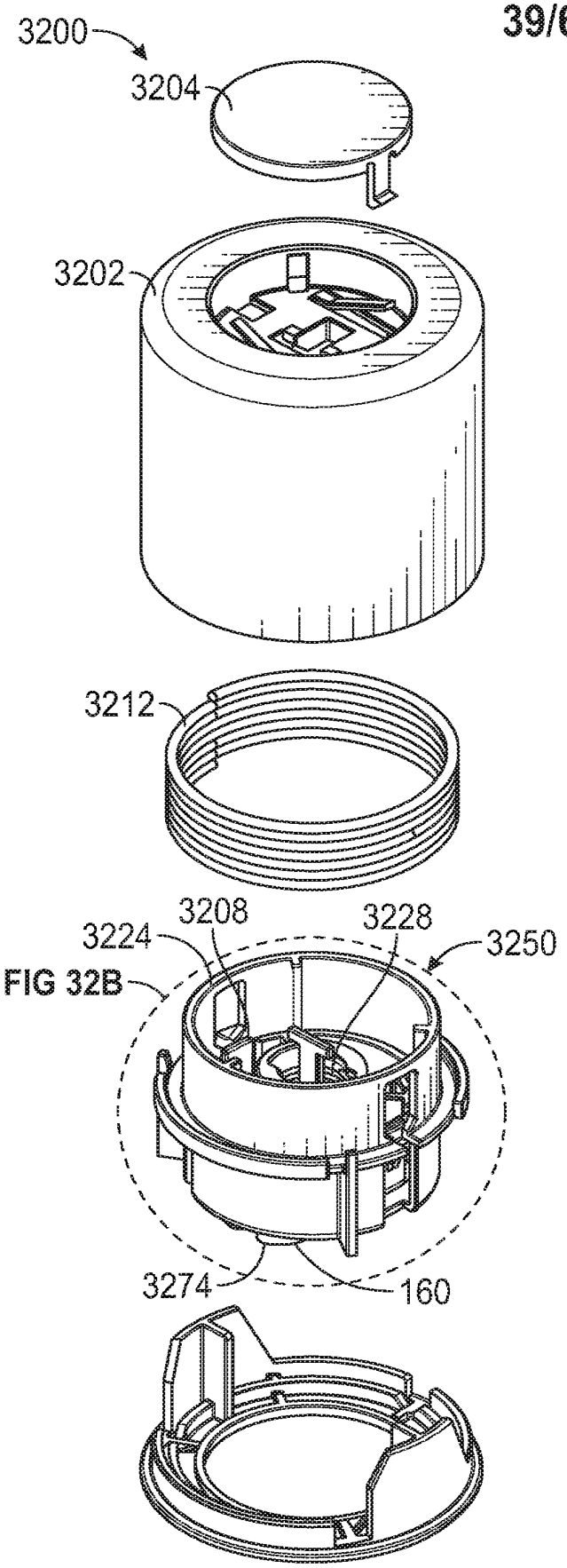


FIG. 32A

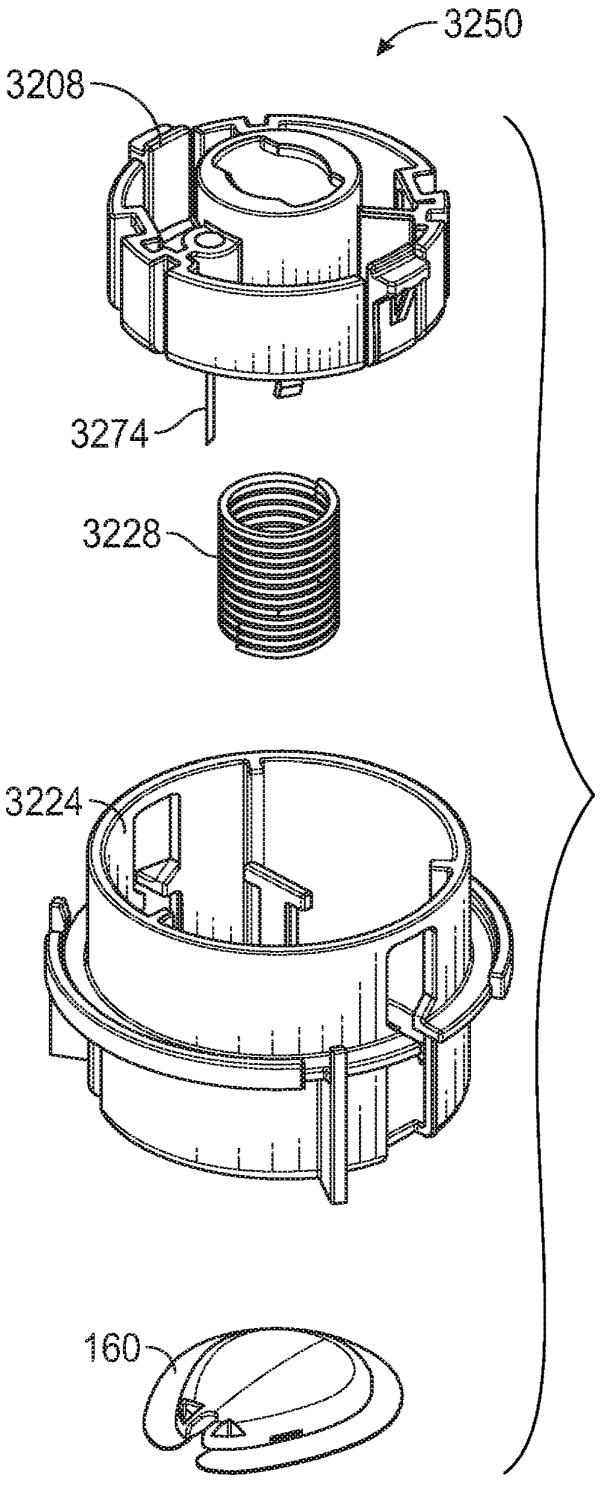


FIG. 32B

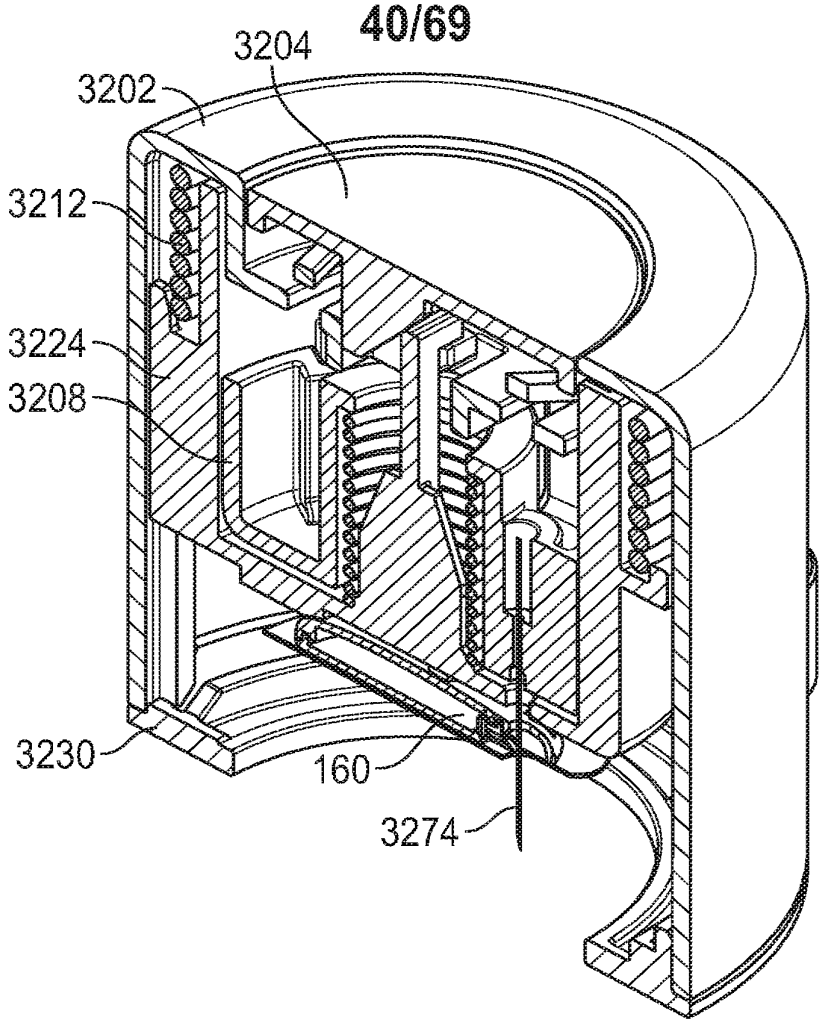


FIG. 33A

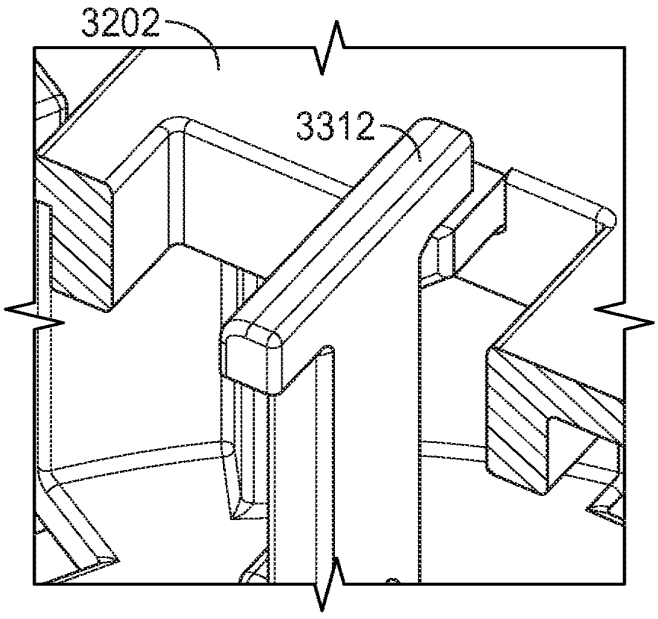


FIG. 33B

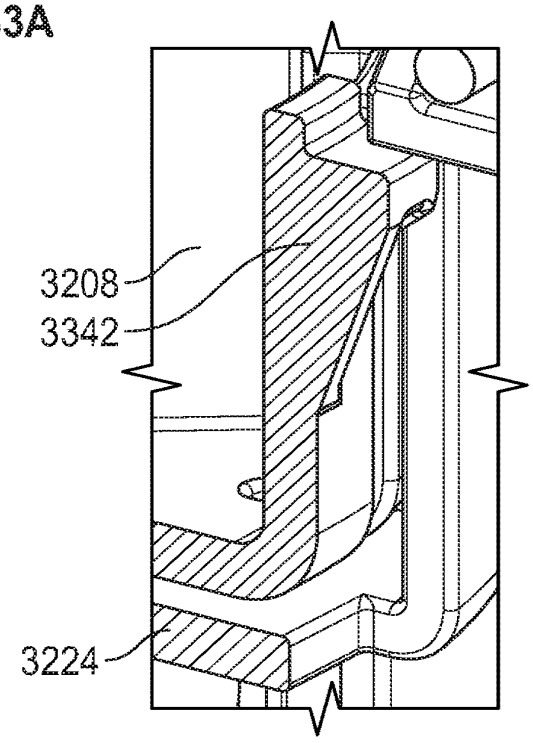


FIG. 33C

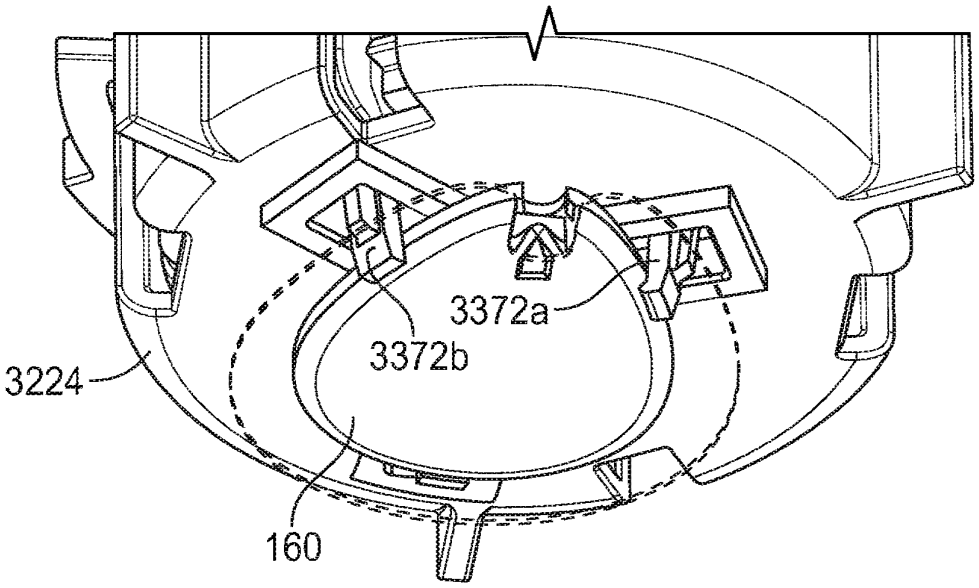


FIG. 33D

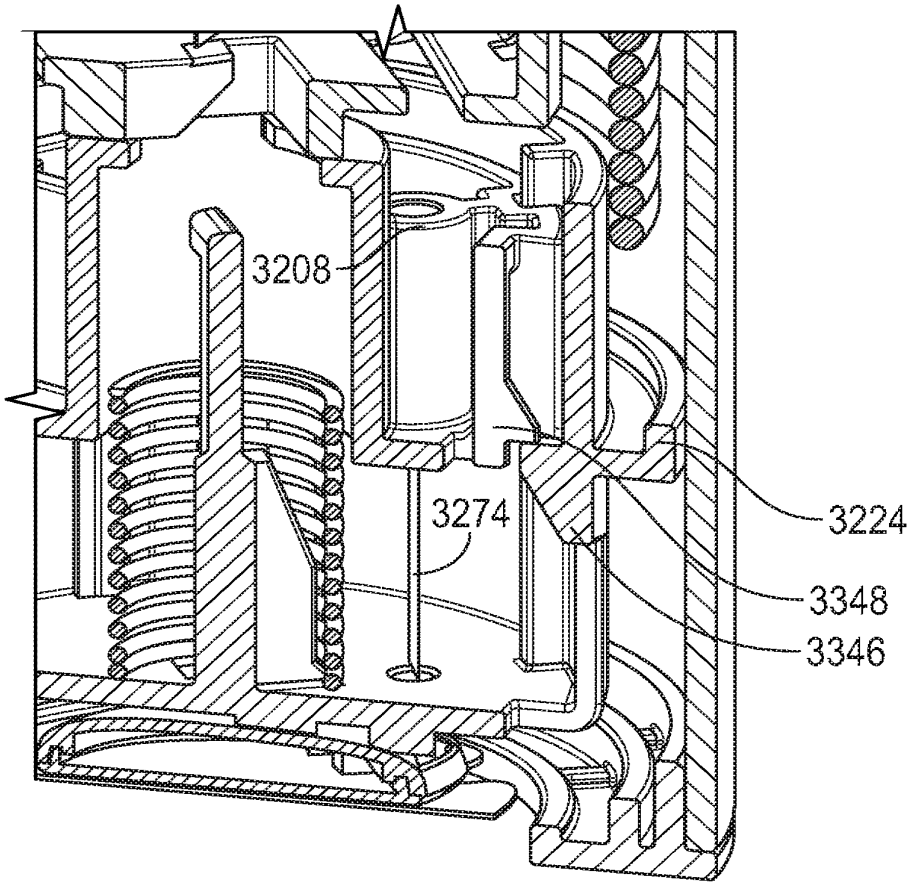


FIG. 33E

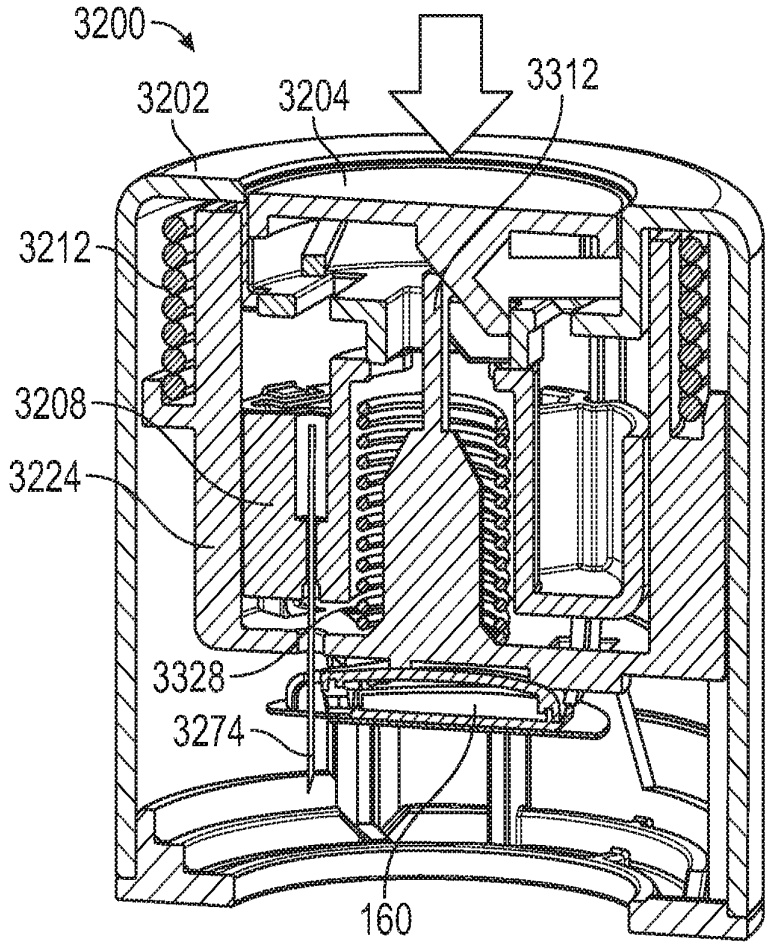


FIG. 34A

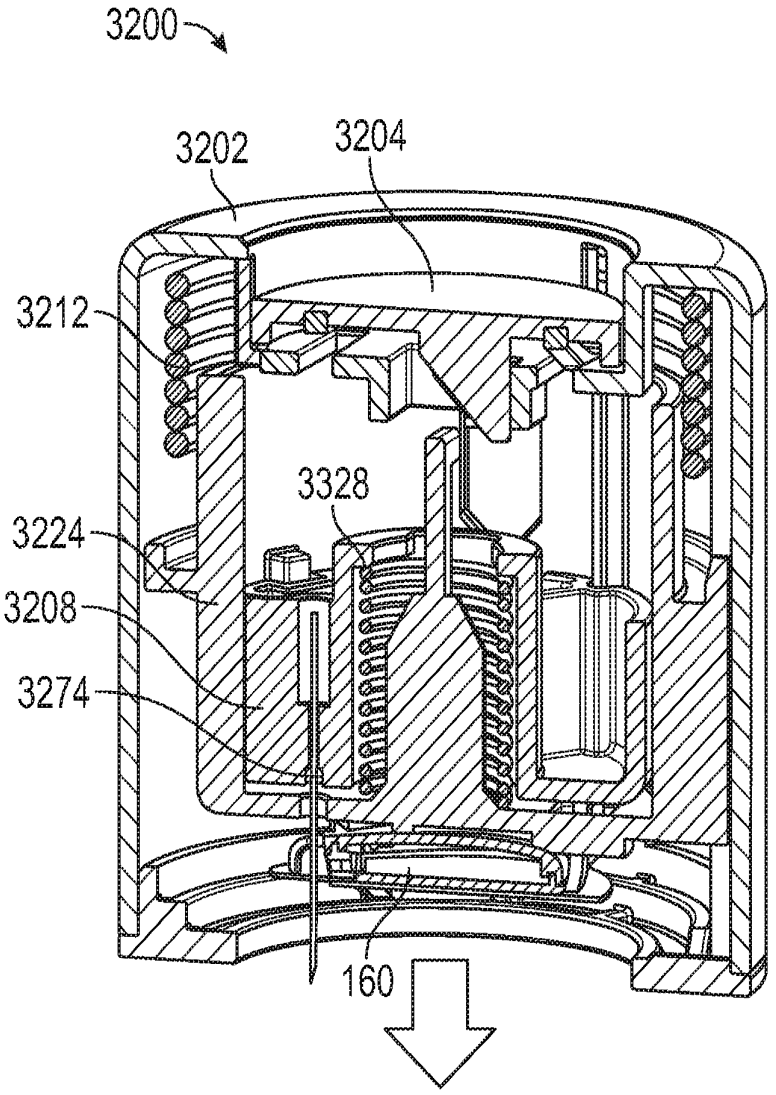


FIG. 34B

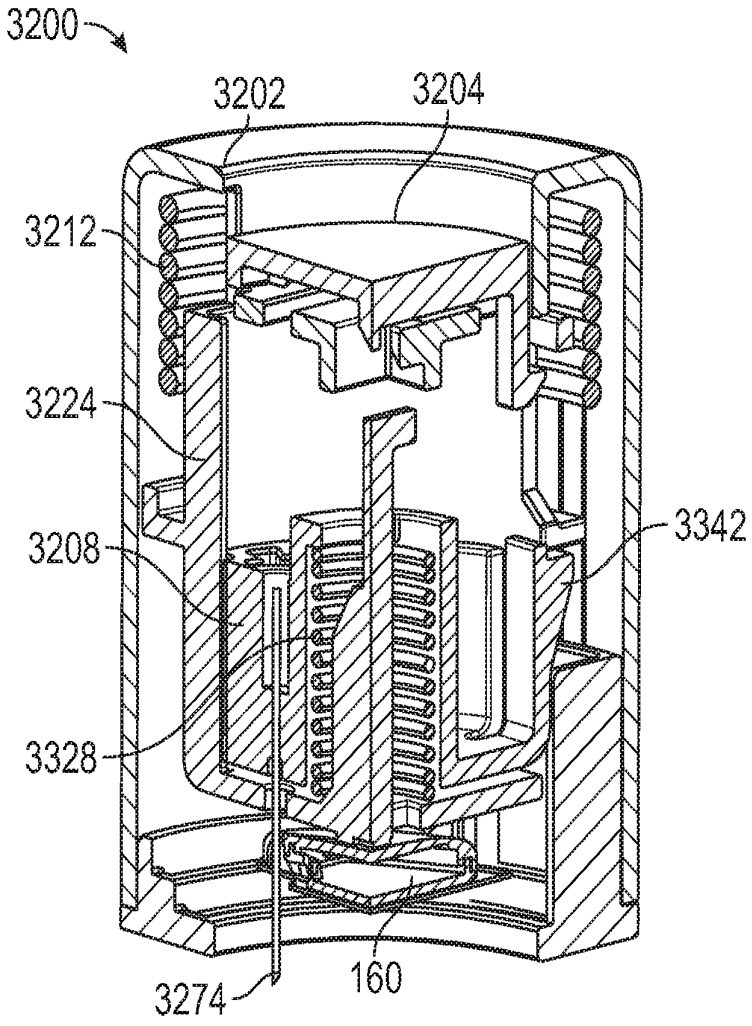


FIG. 34C

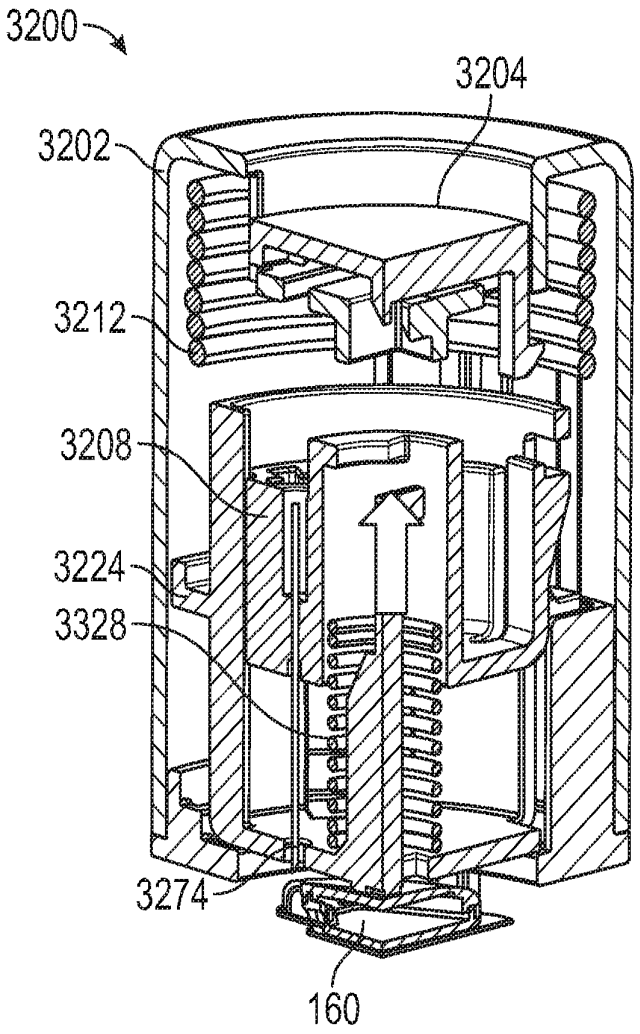


FIG. 34D

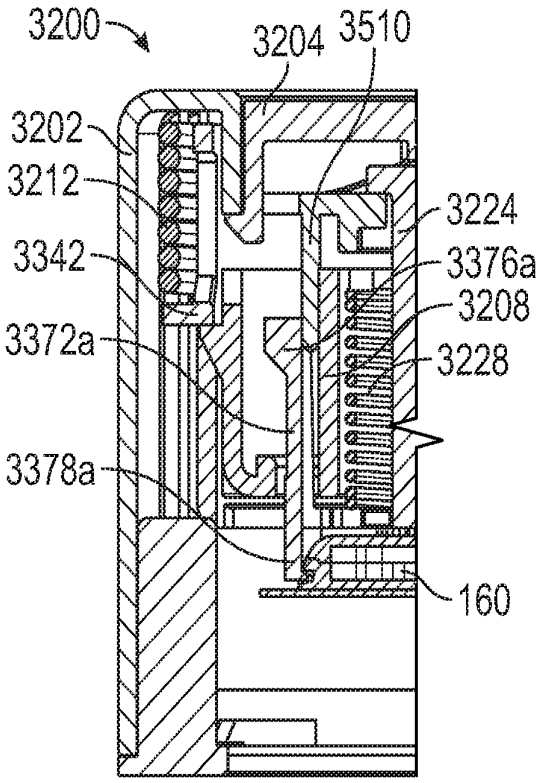


FIG. 35A

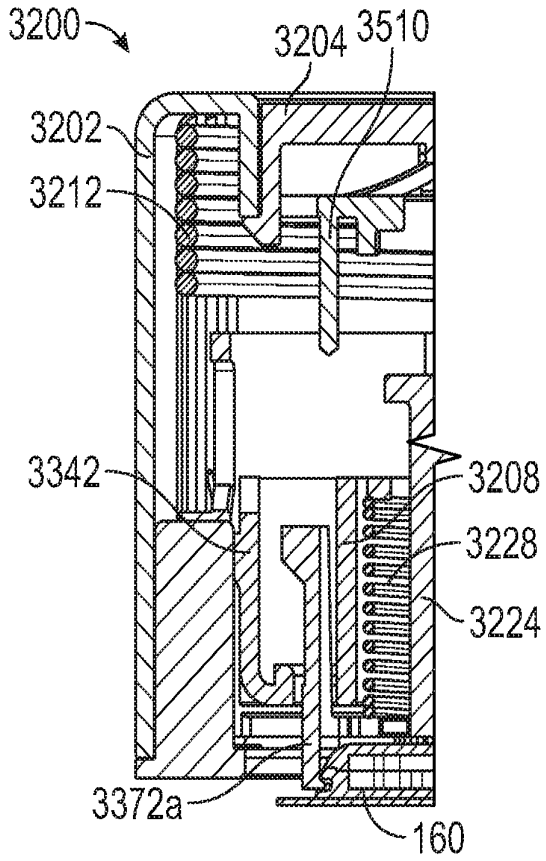


FIG. 35B

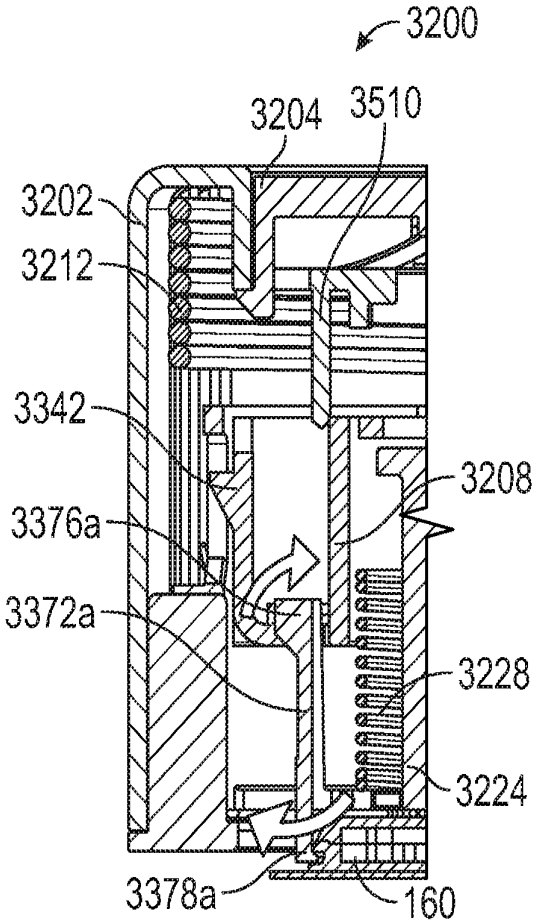


FIG. 35C

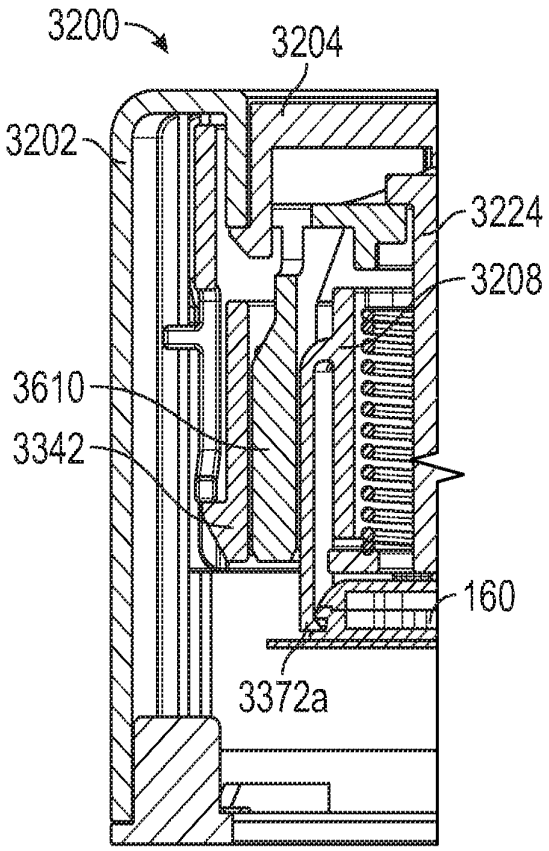


FIG. 36A

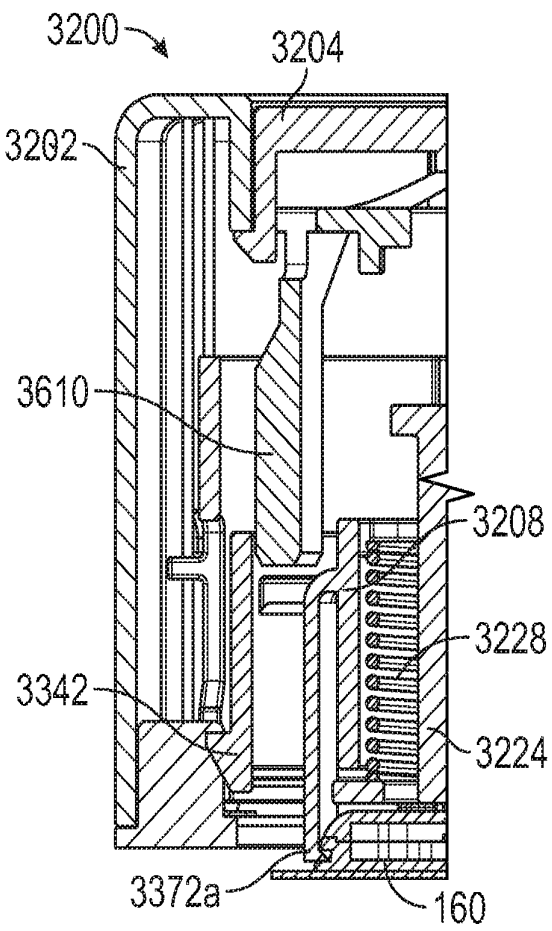


FIG. 36B

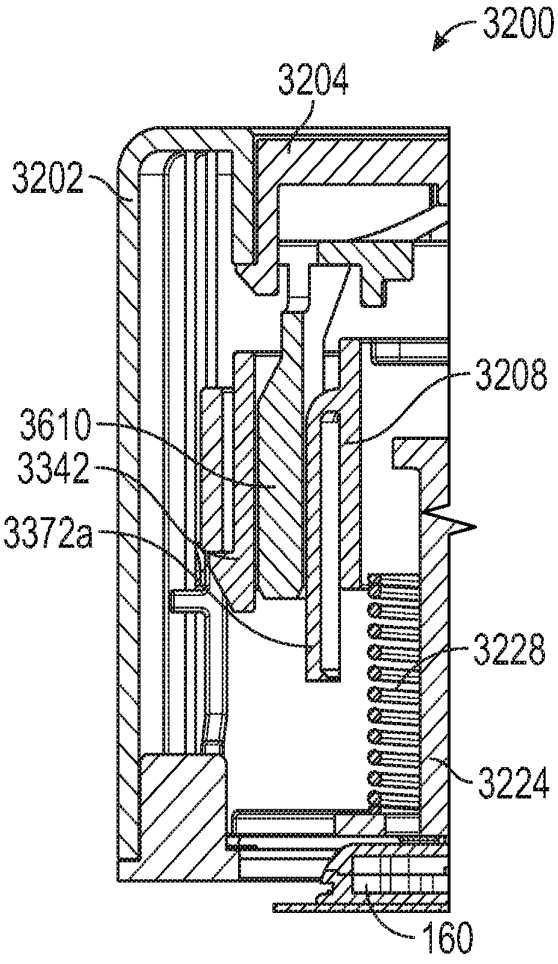


FIG. 36C

Abbott Ex. 1003 - 76/532

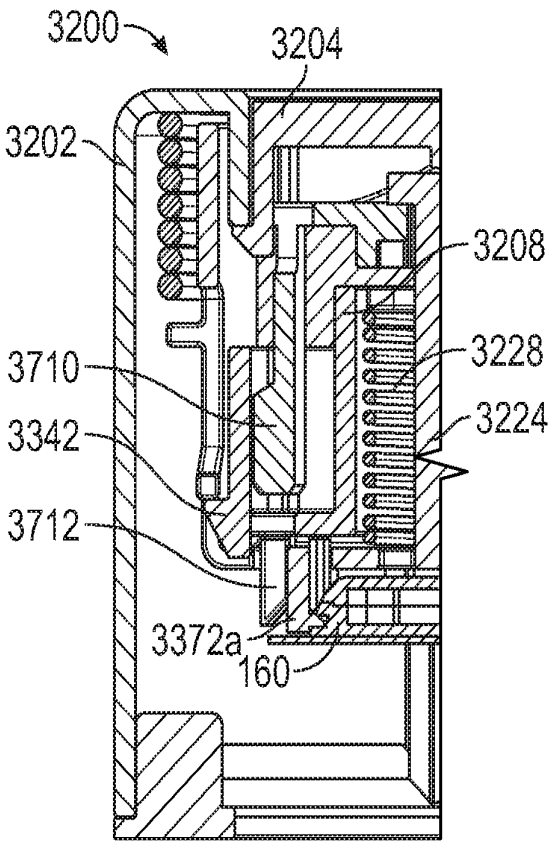


FIG. 37A

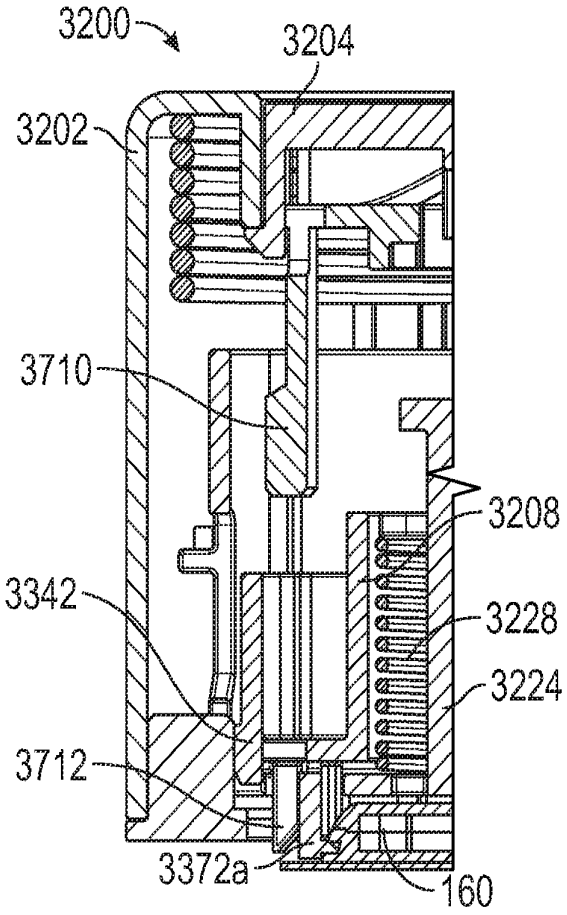


FIG. 37B

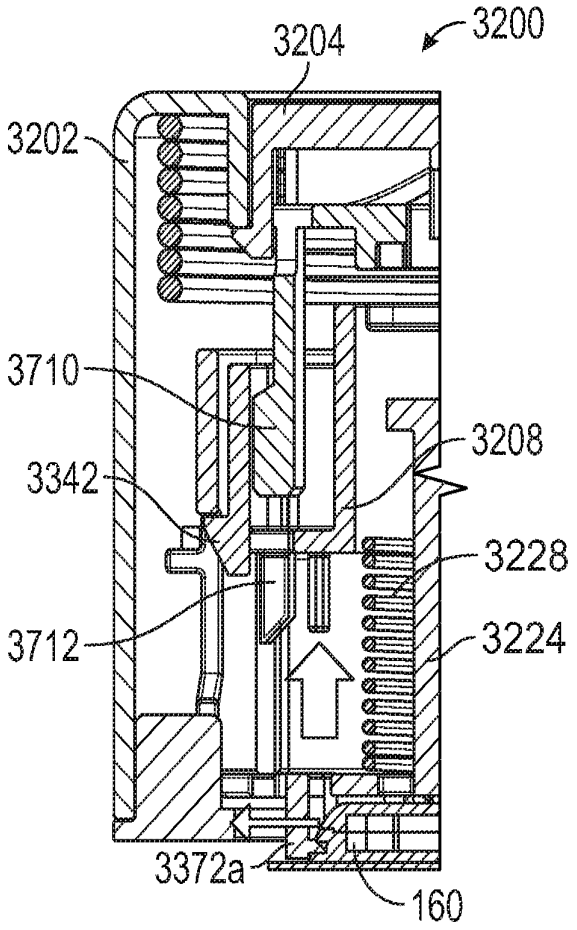


FIG. 37C

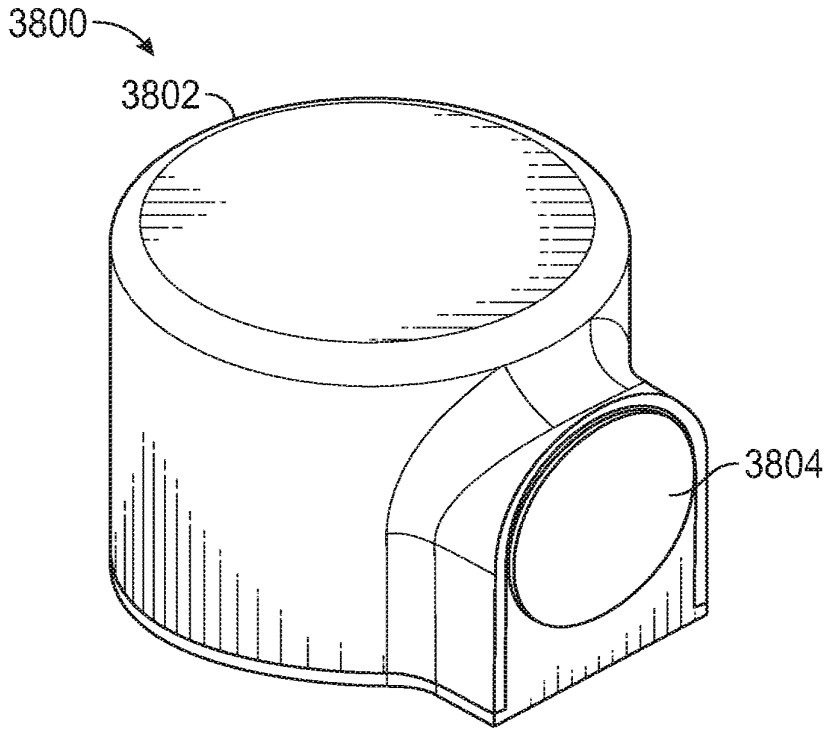


FIG. 38

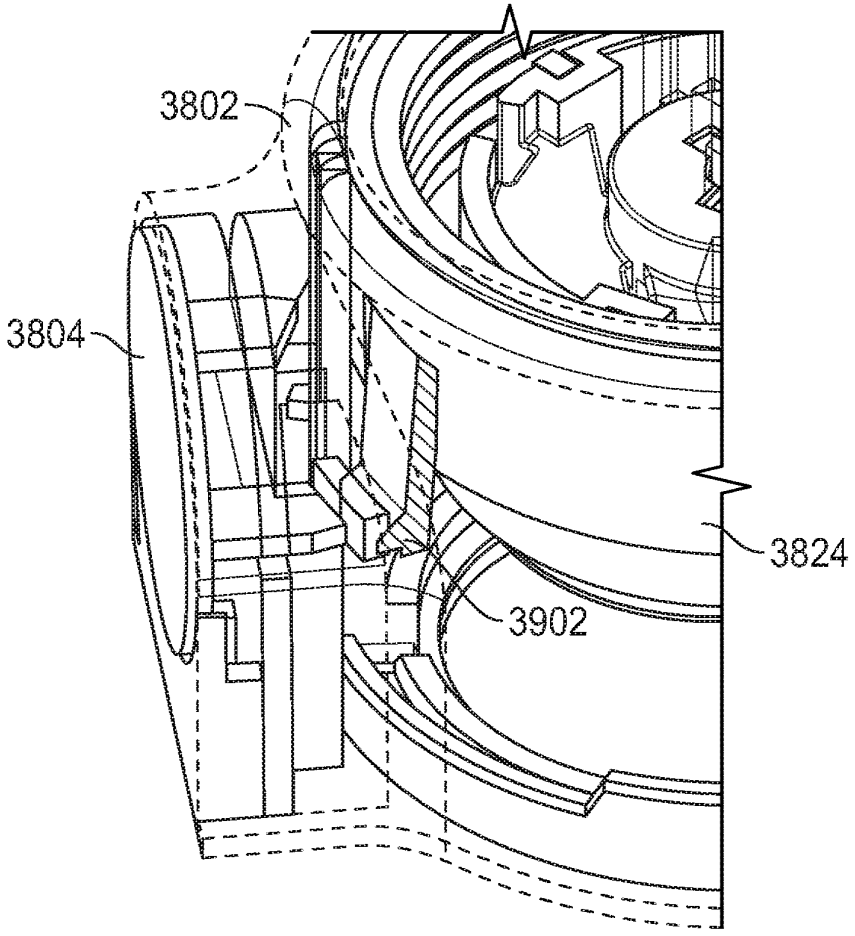


FIG. 39

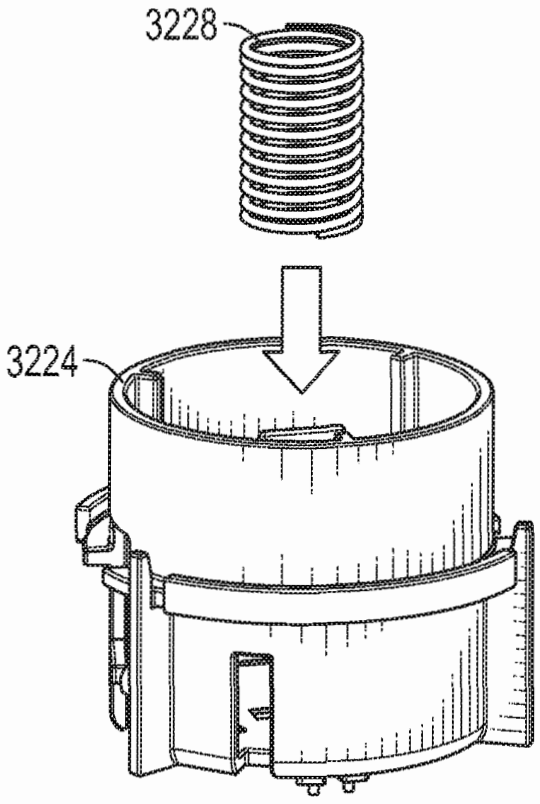


FIG. 40A

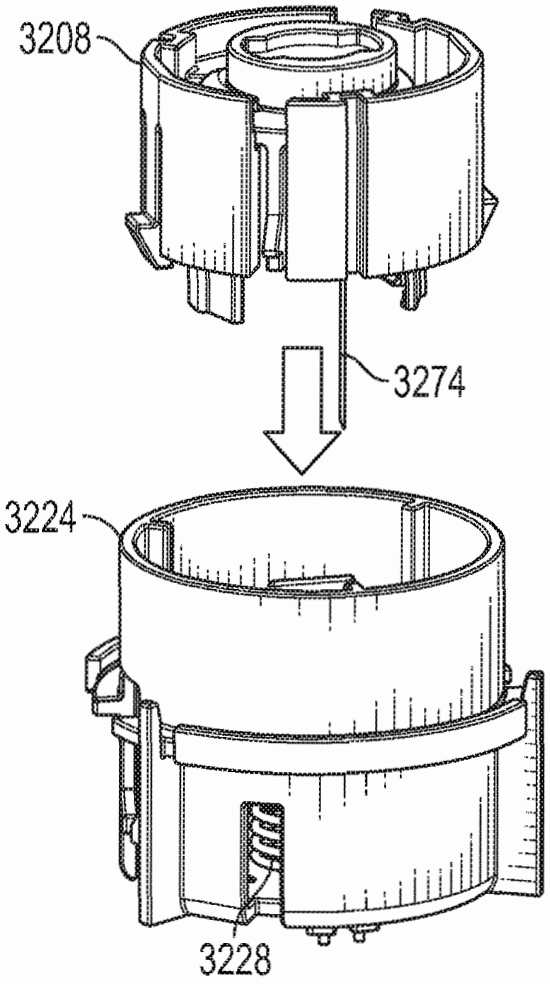


FIG. 40B

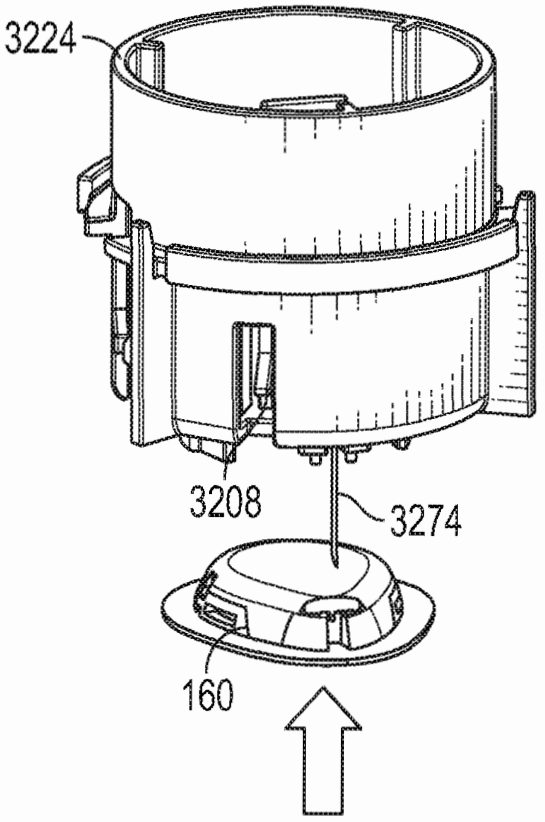


FIG. 40C

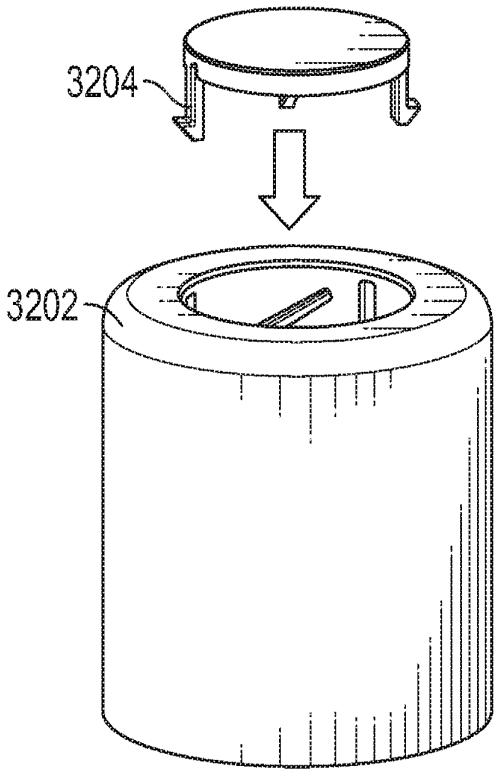


FIG. 40D

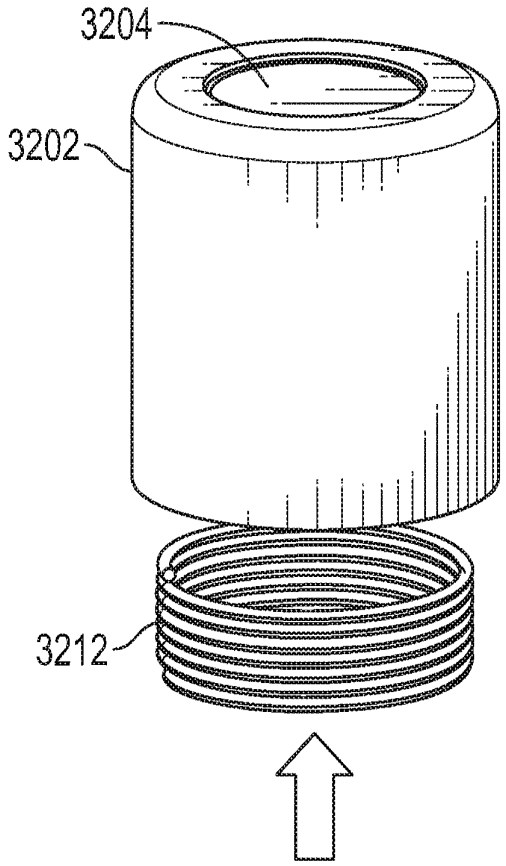


FIG. 40E

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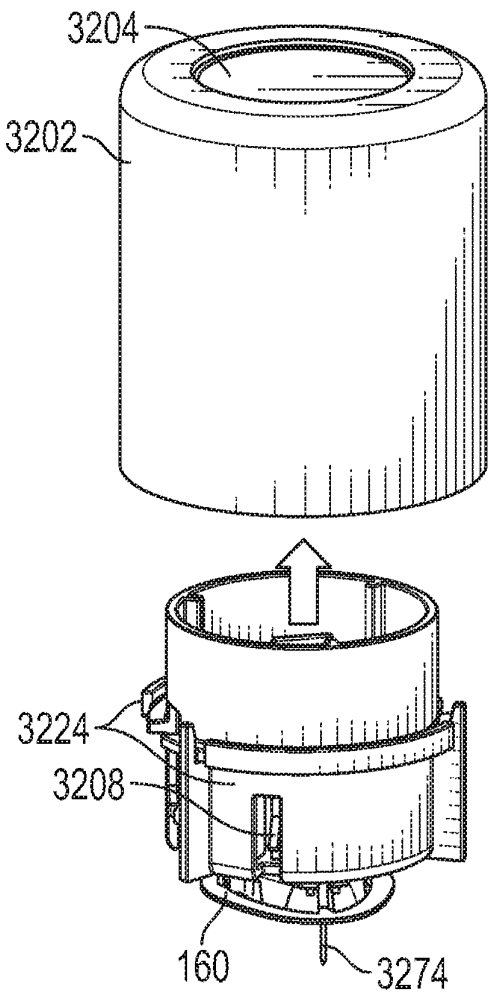


FIG. 40F

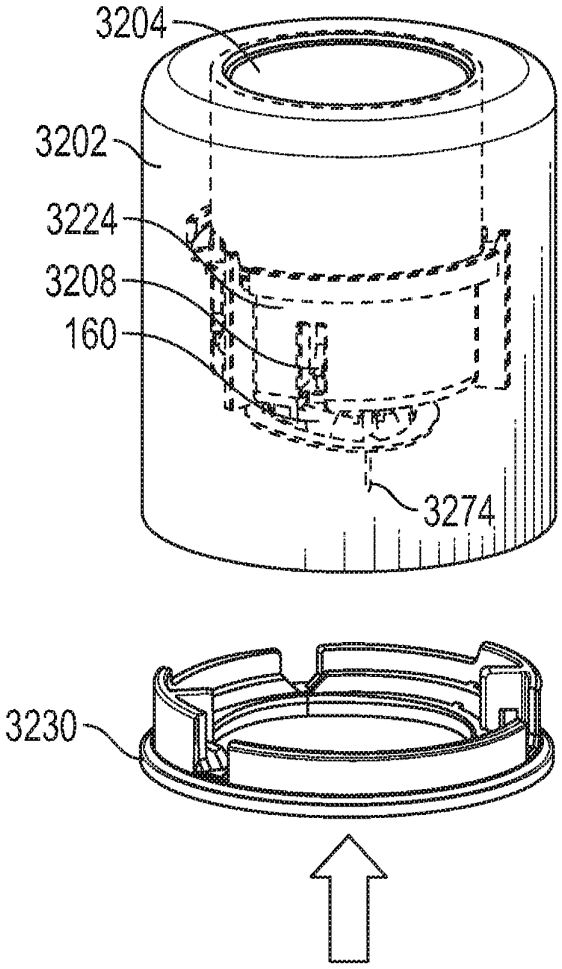


FIG. 40G

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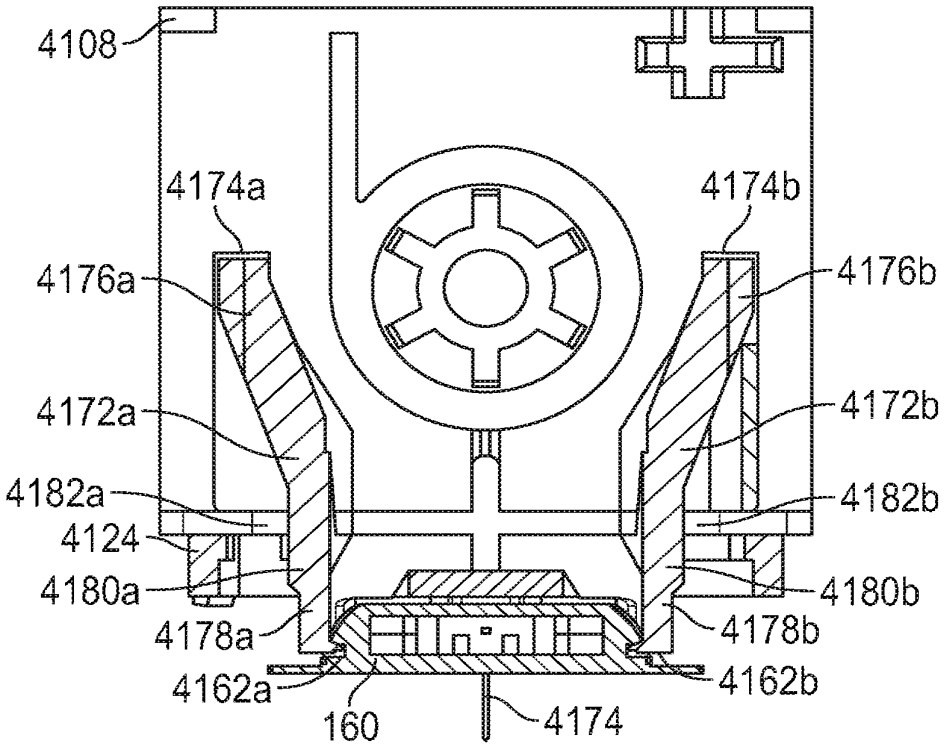


FIG. 41A

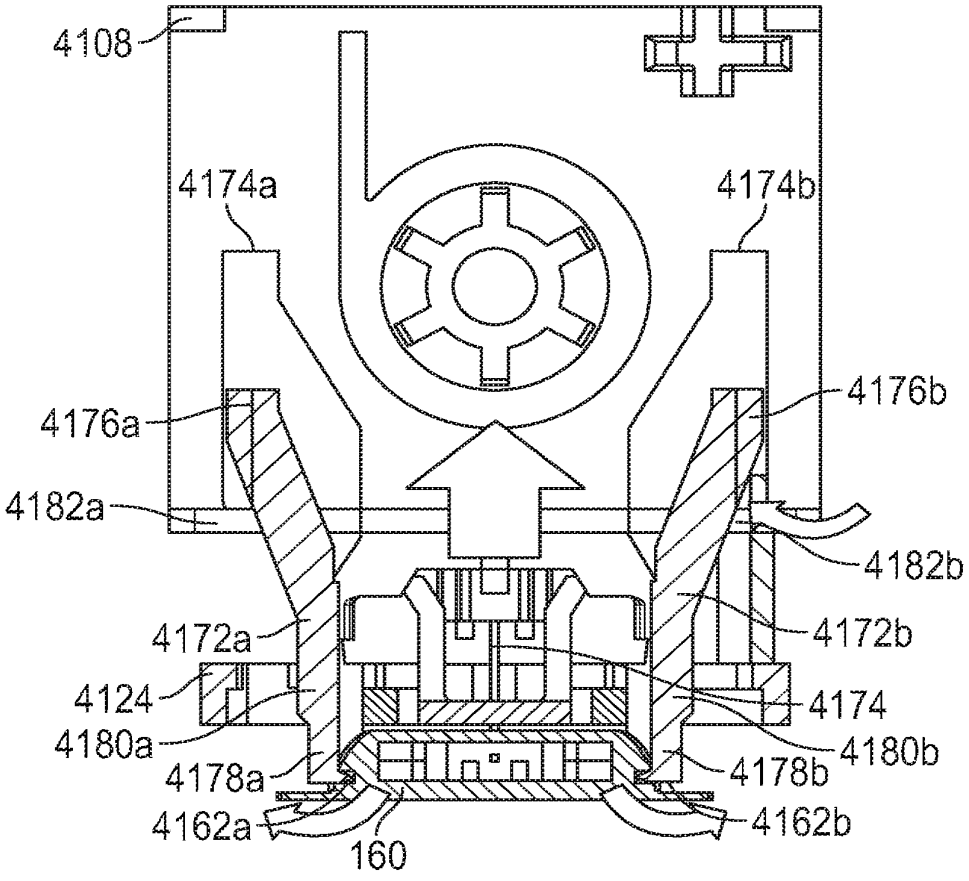


FIG. 41B

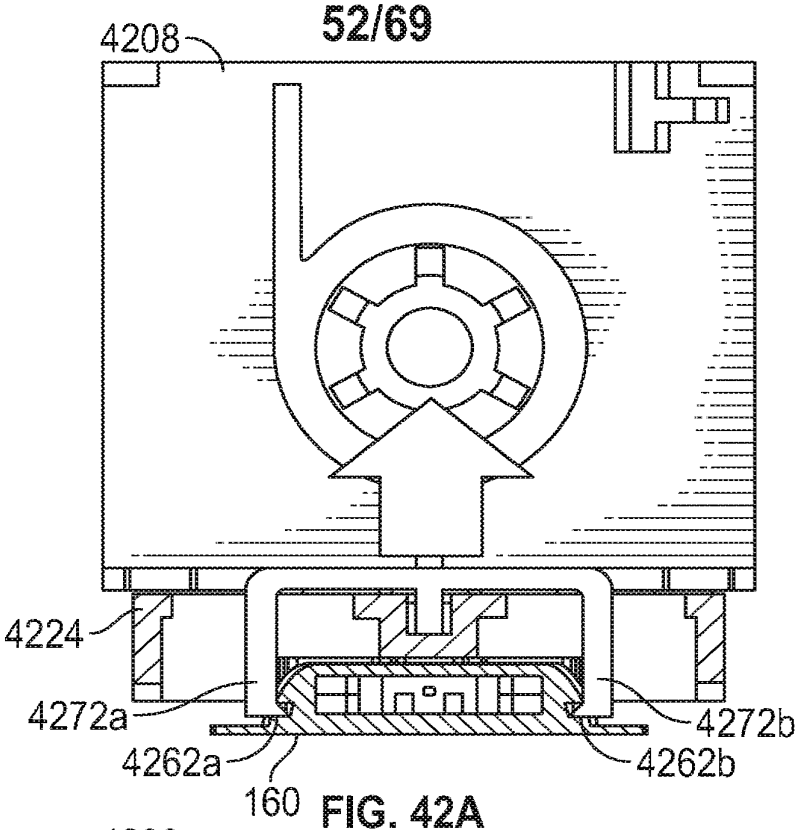


FIG. 42A

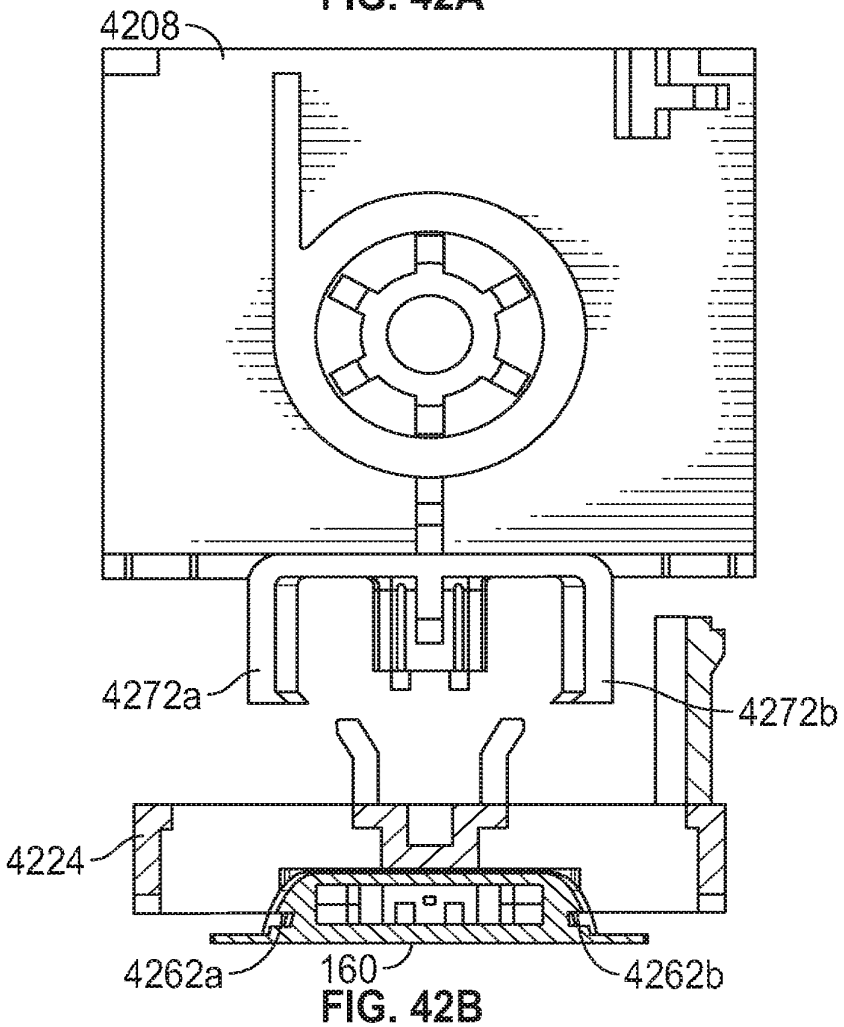


FIG. 42B

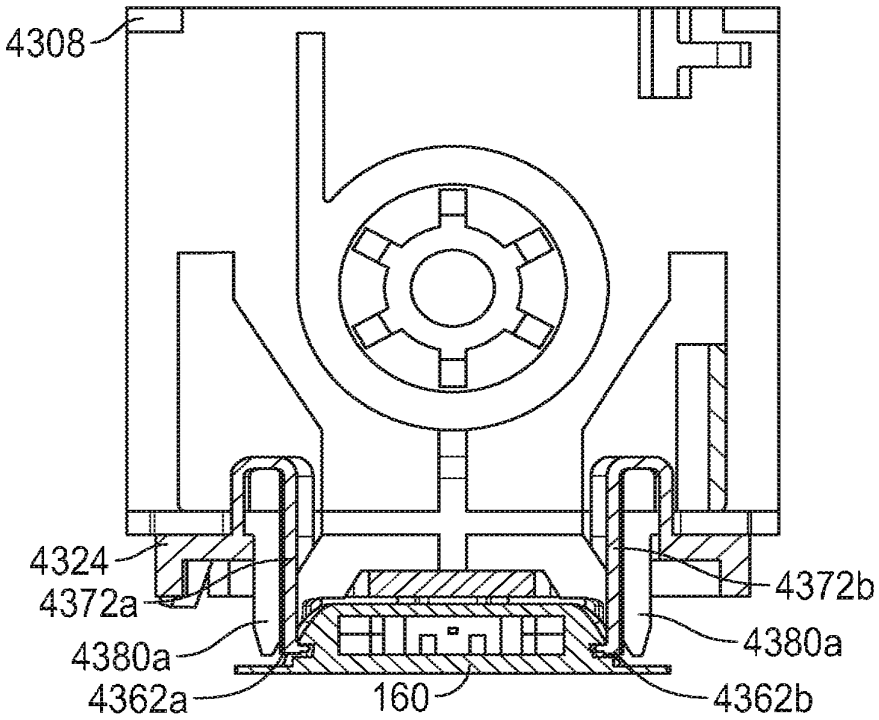


FIG. 43A

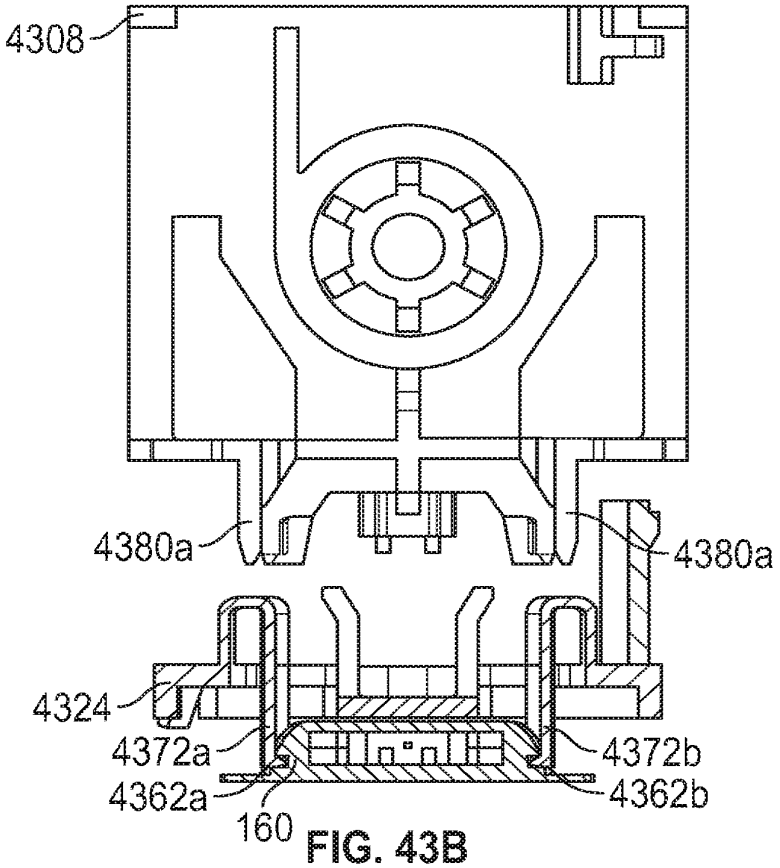


FIG. 43B

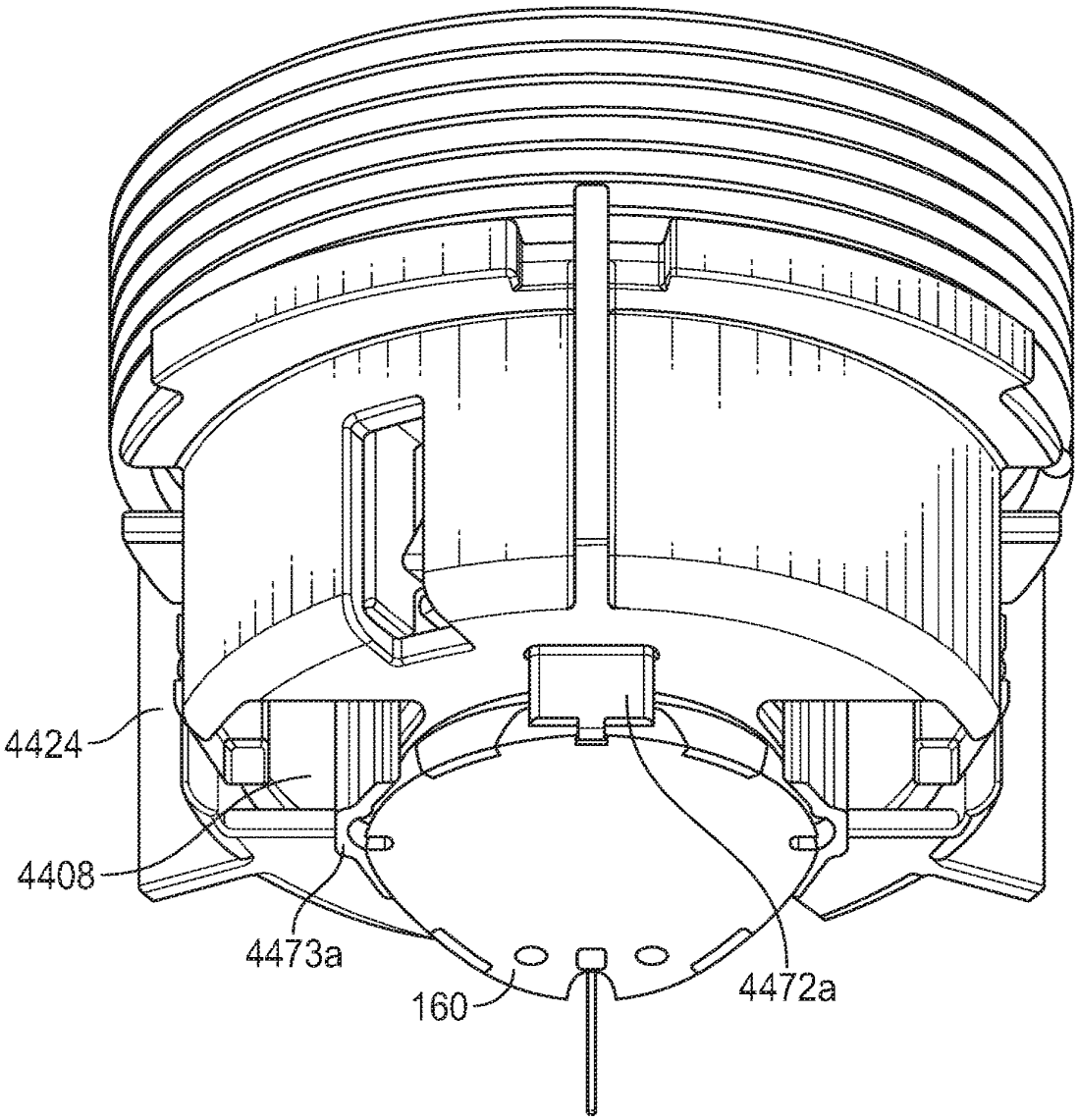


FIG. 44

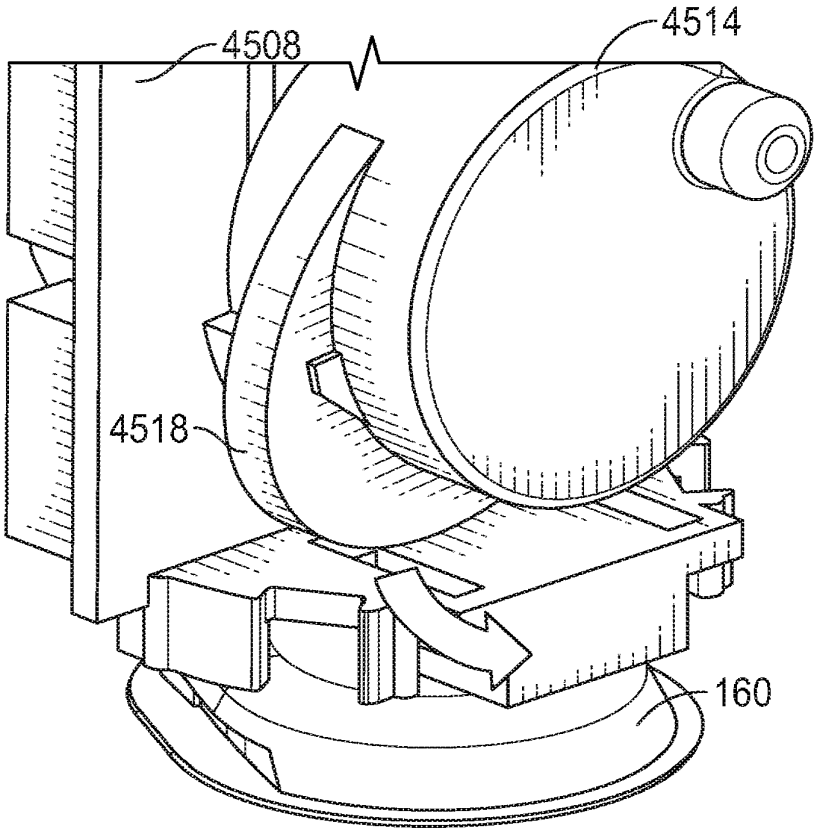


FIG. 45

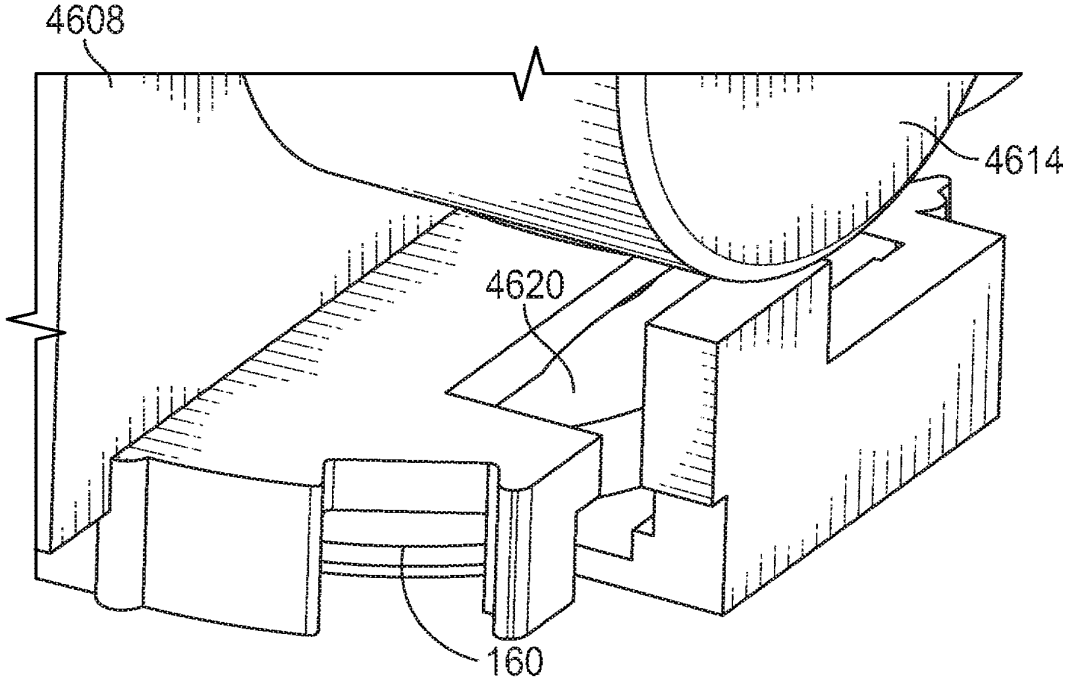


FIG. 46

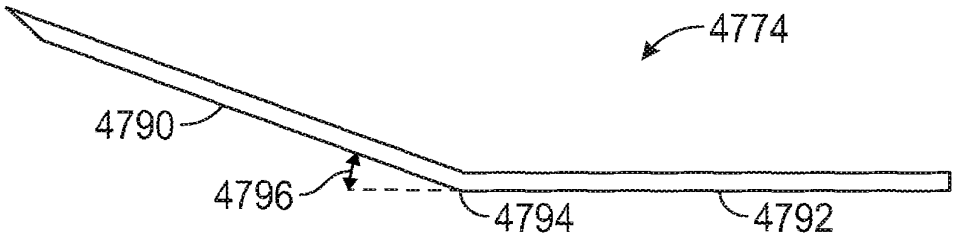


FIG. 47

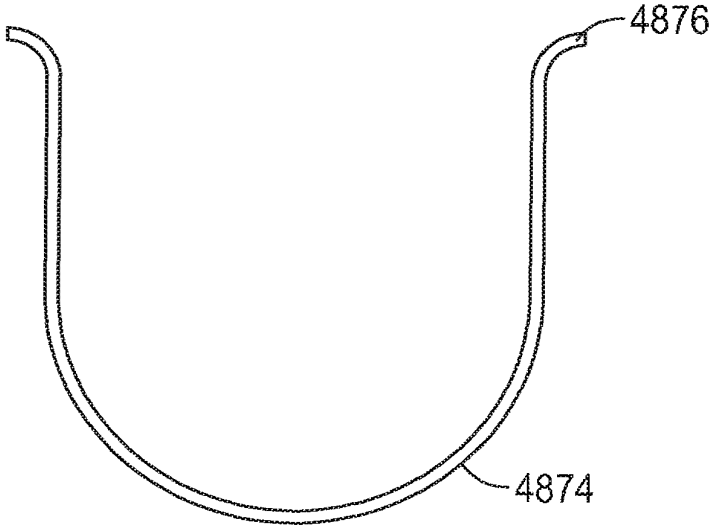


FIG. 48A

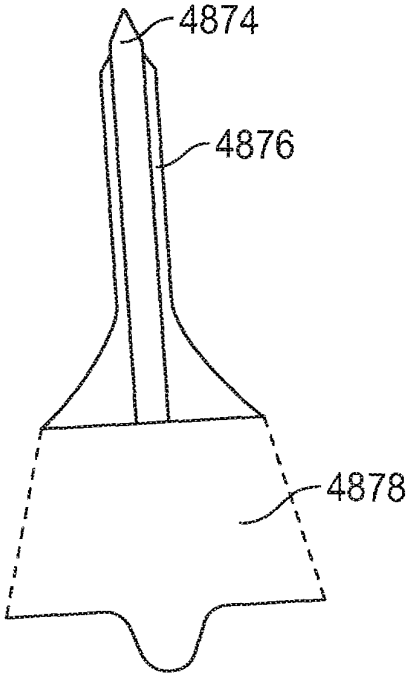


FIG. 48B

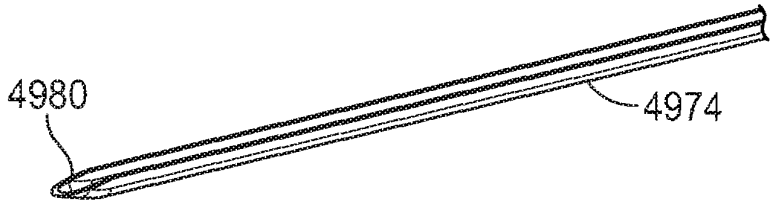


FIG. 49



FIG. 50

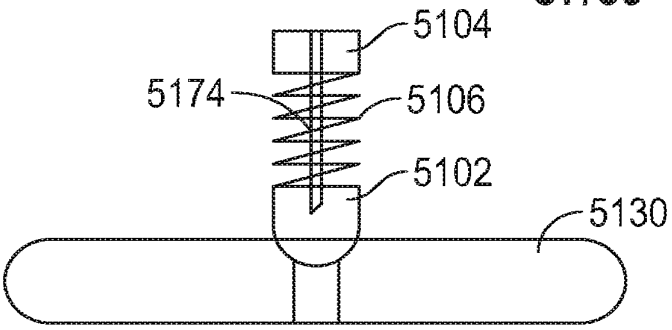


FIG. 51A

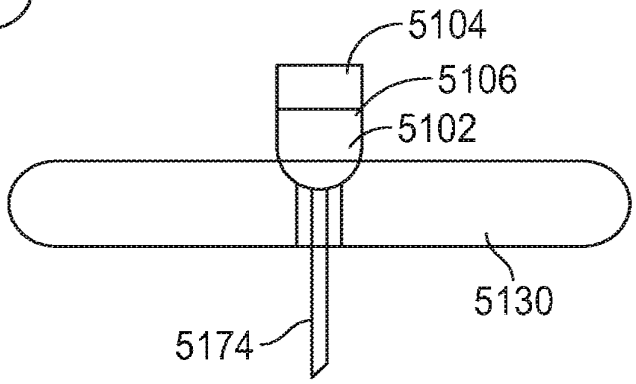


FIG. 51B

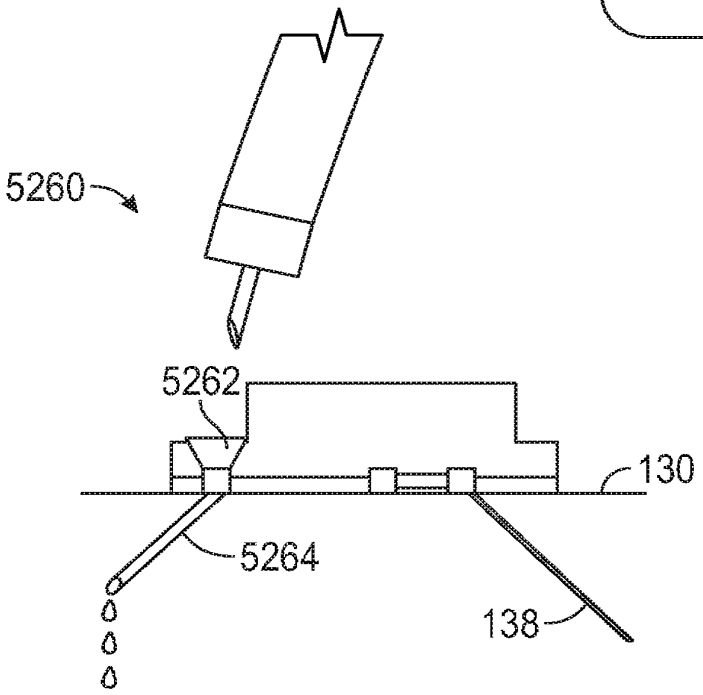


FIG. 52A

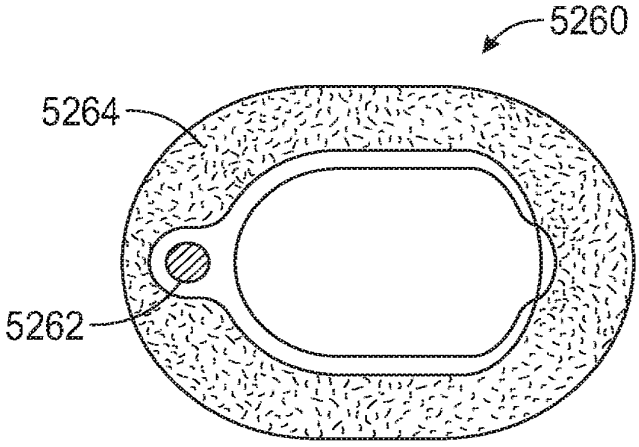


FIG. 52B

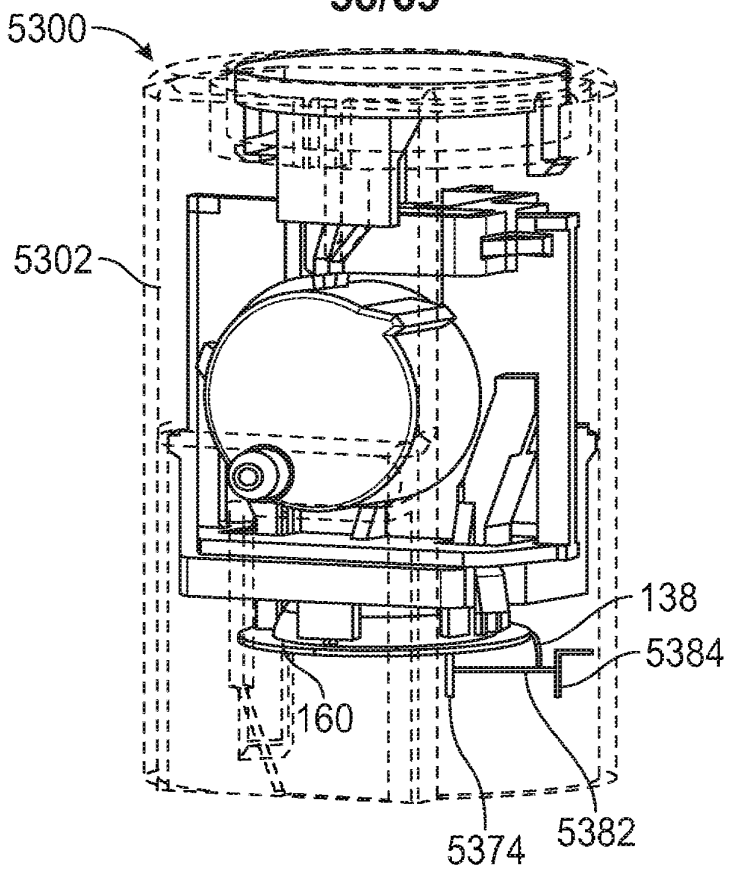


FIG. 53

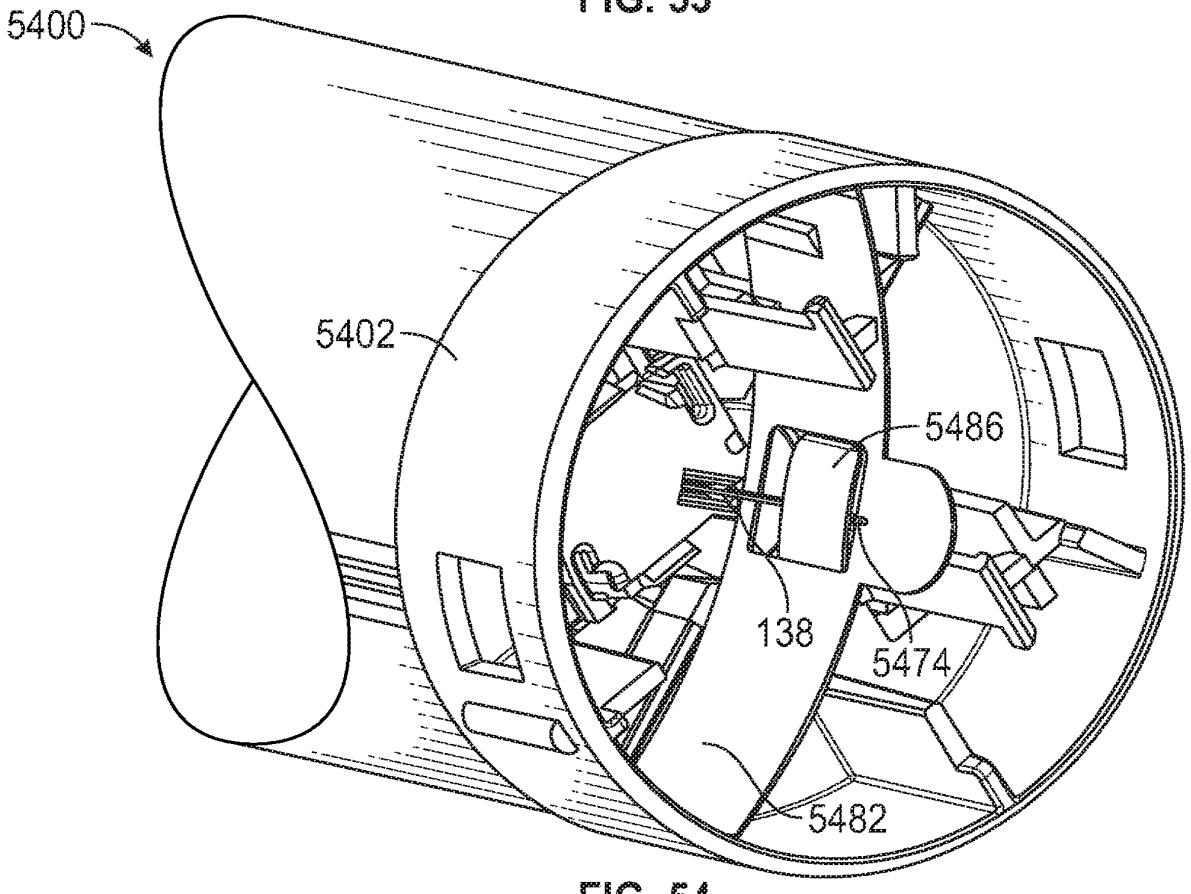


FIG. 54

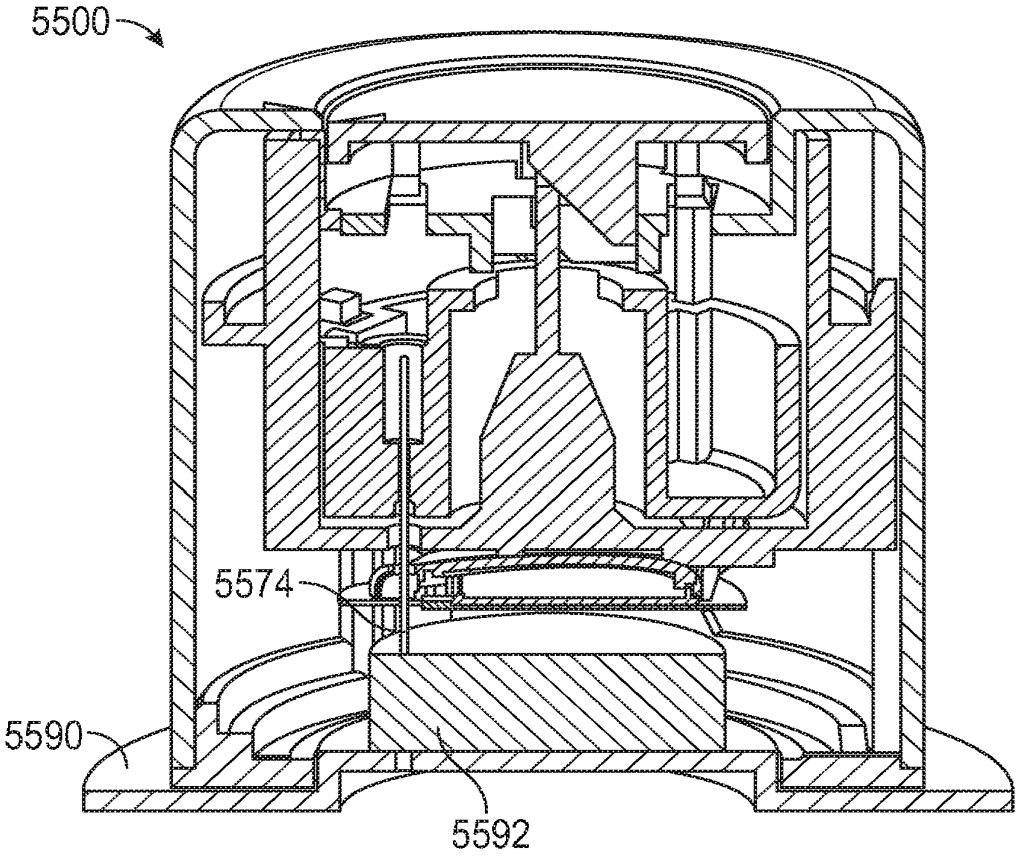


FIG. 55

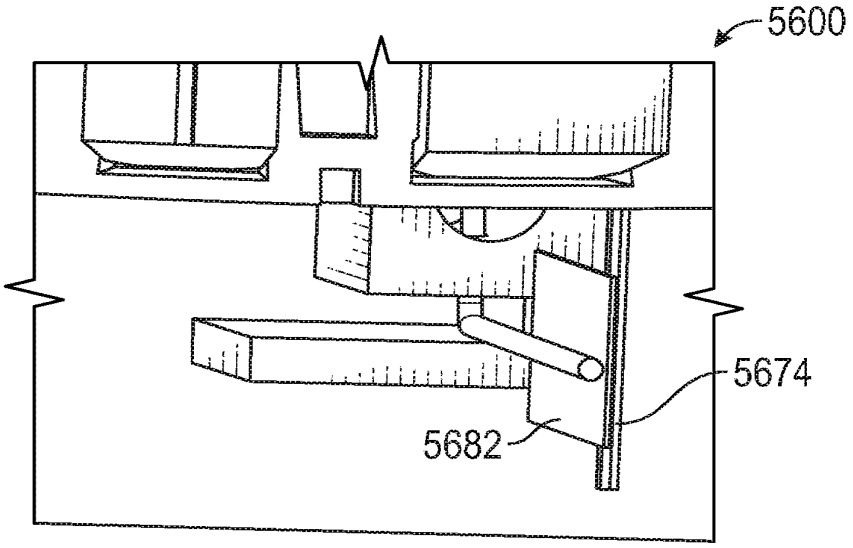


FIG. 56A

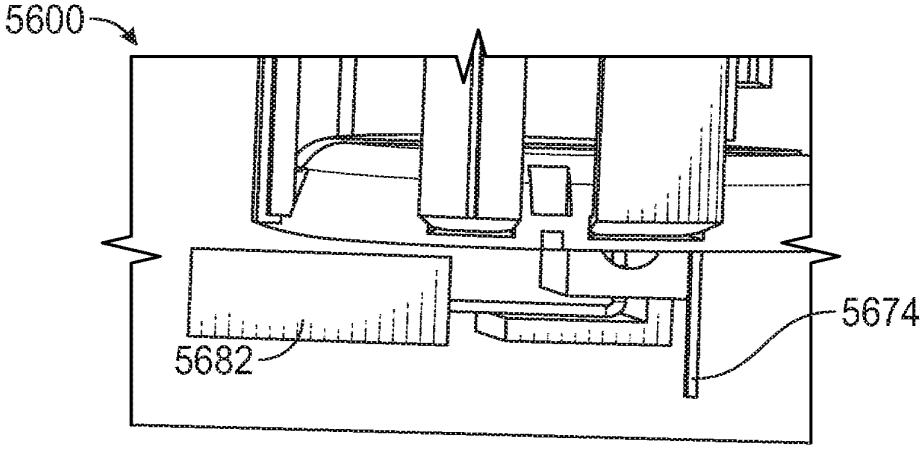


FIG. 56B

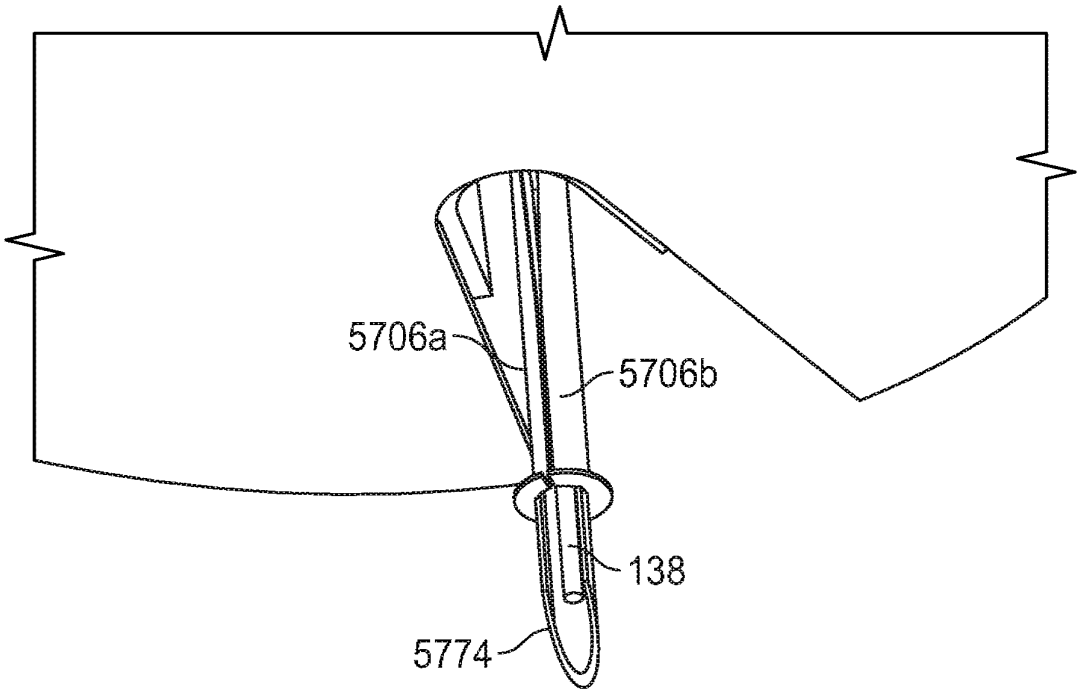


FIG. 57

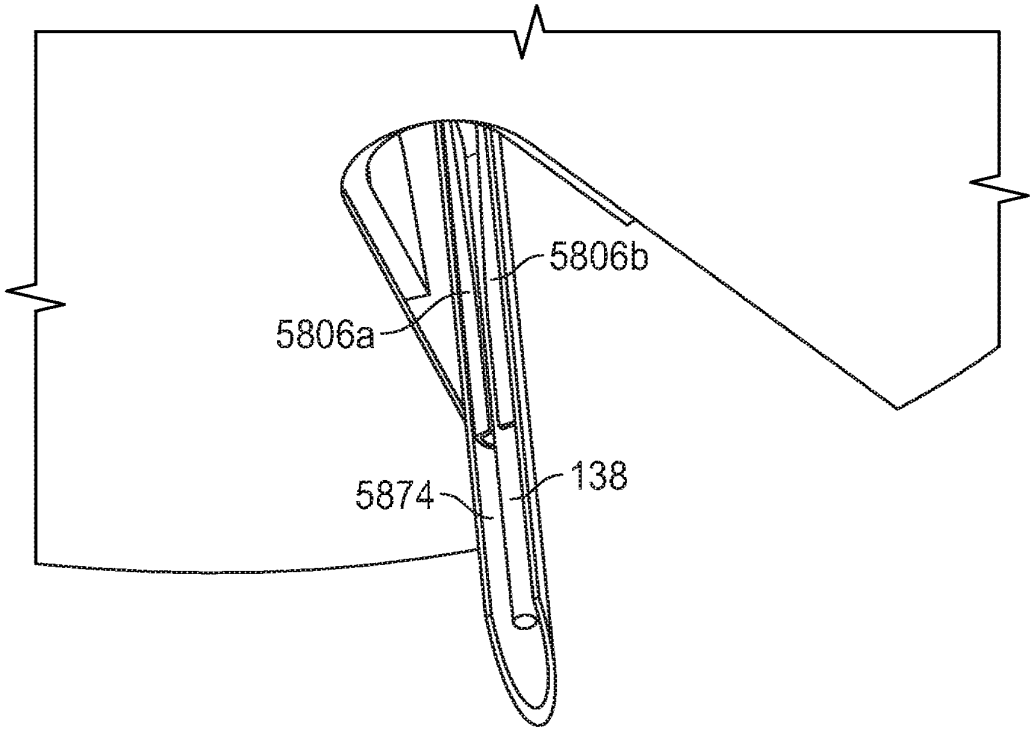


FIG. 58

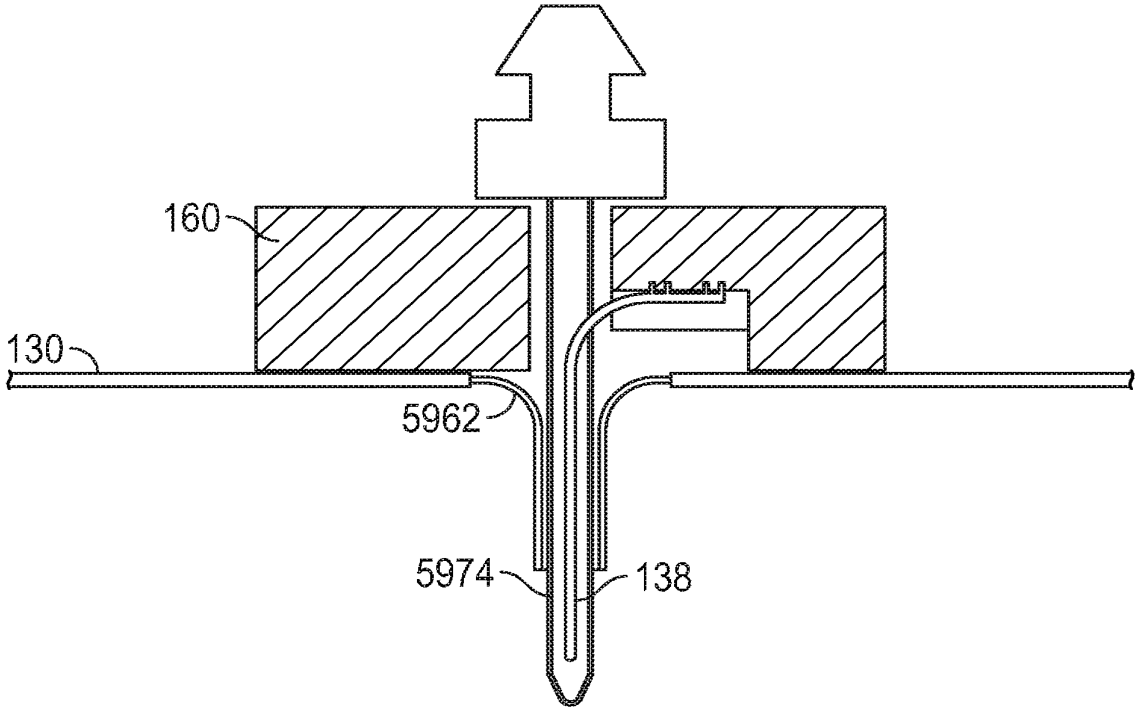


FIG. 59A

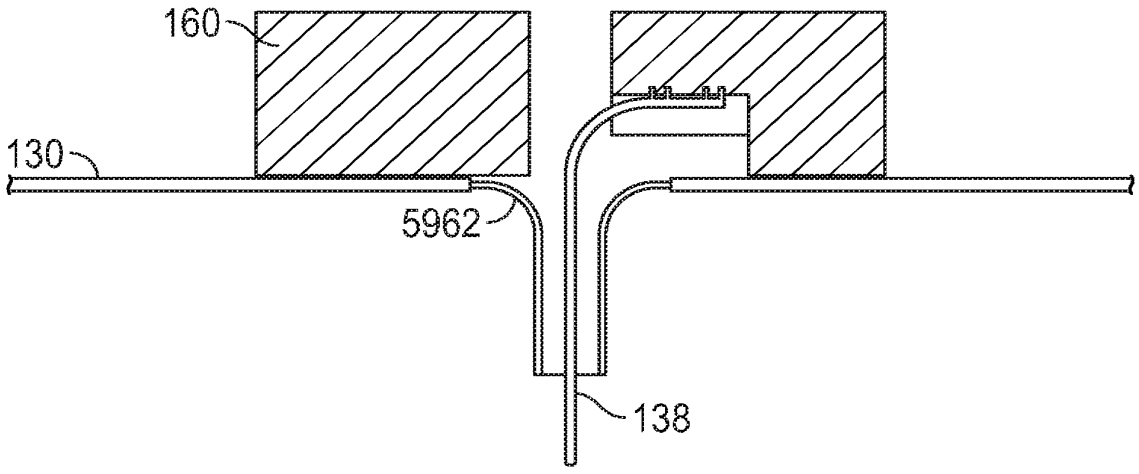


FIG. 59B

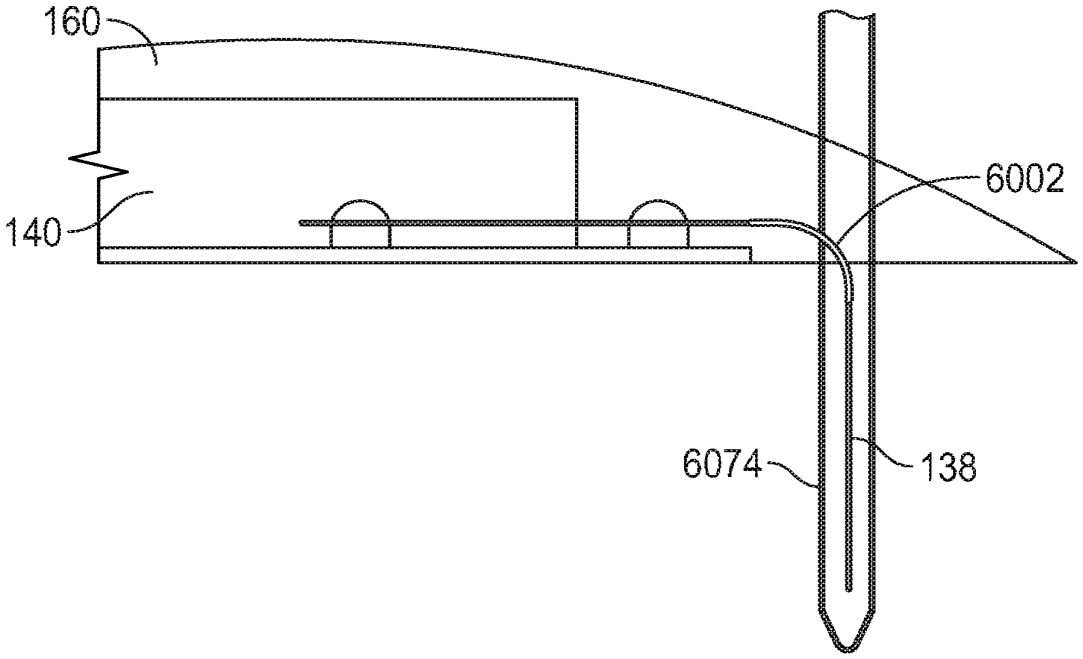


FIG. 60

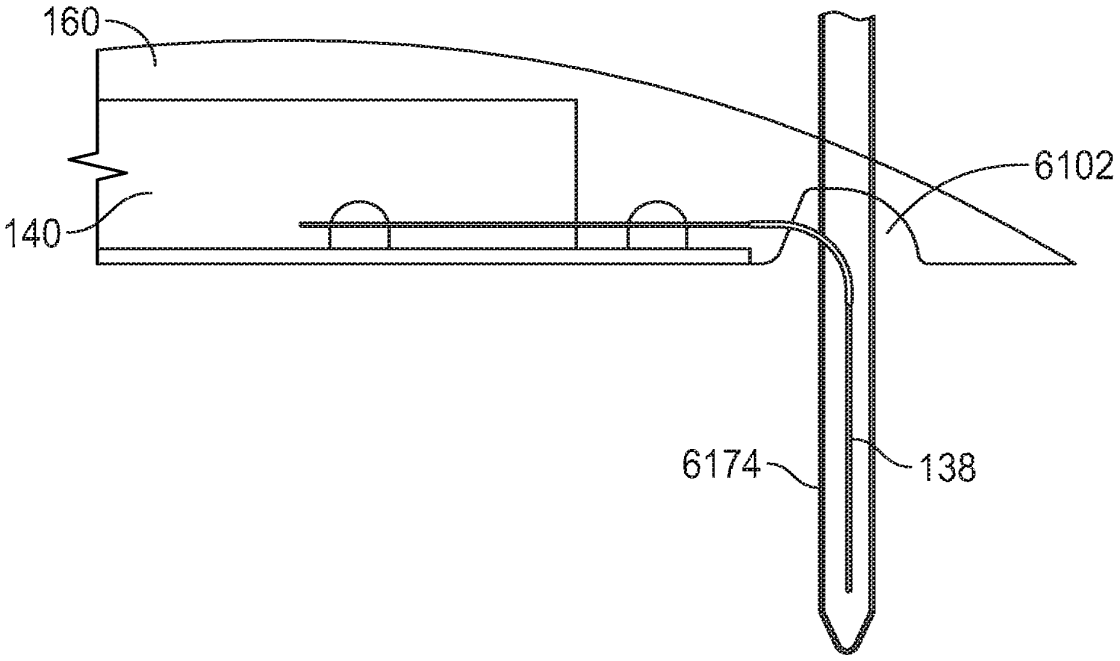


FIG. 61

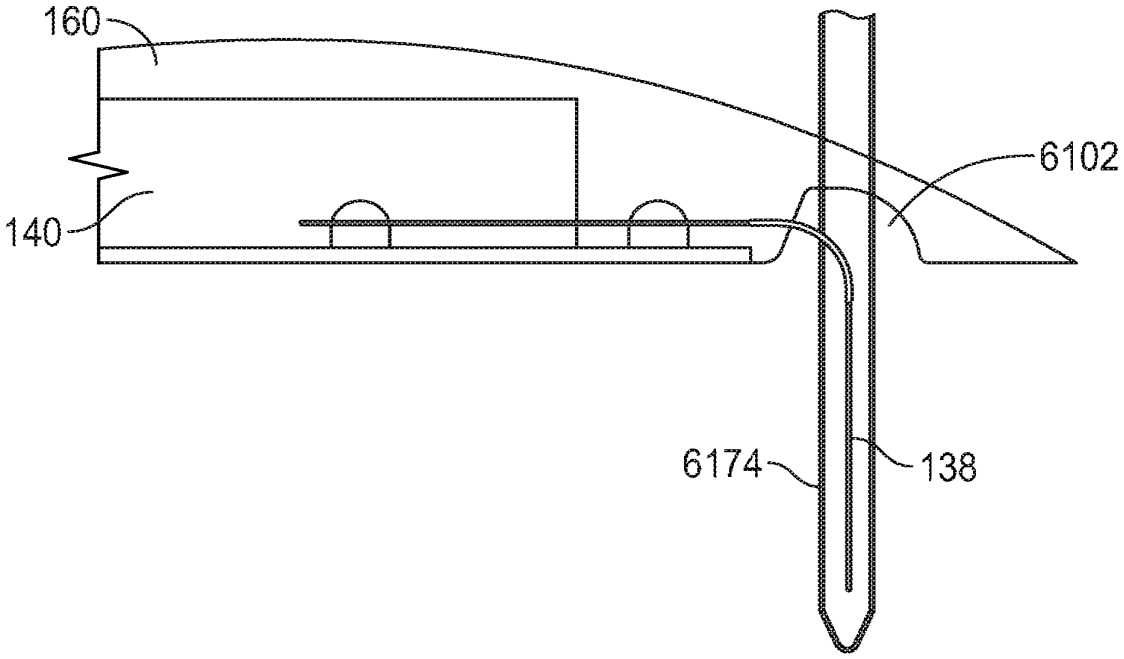


FIG. 62

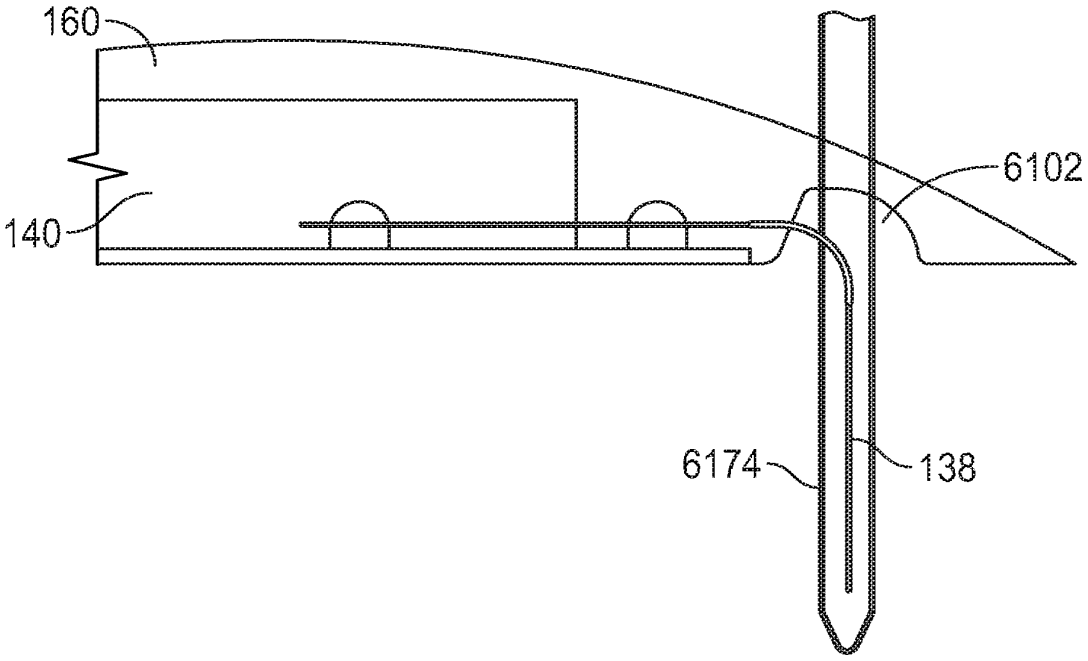


FIG. 63

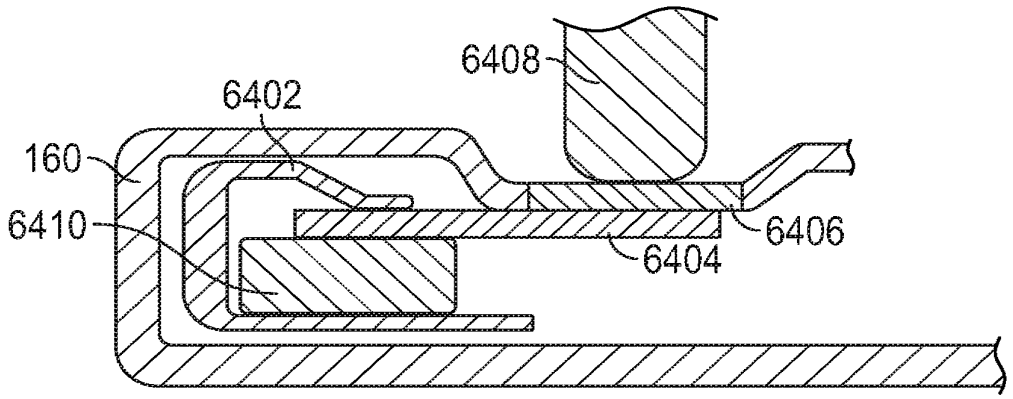


FIG. 64A

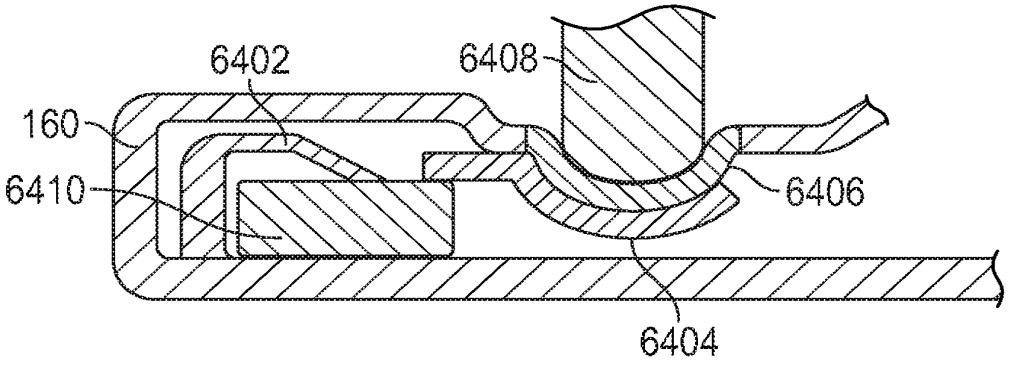


FIG. 64B

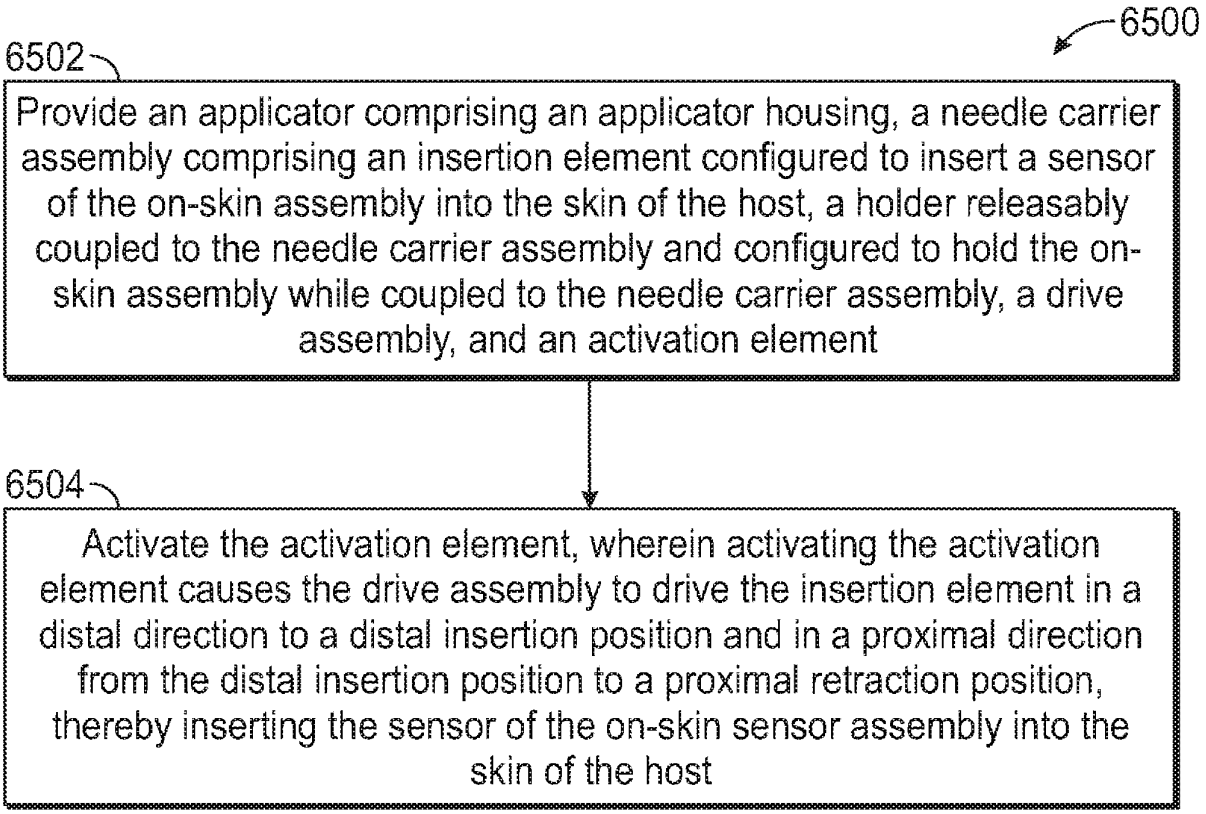
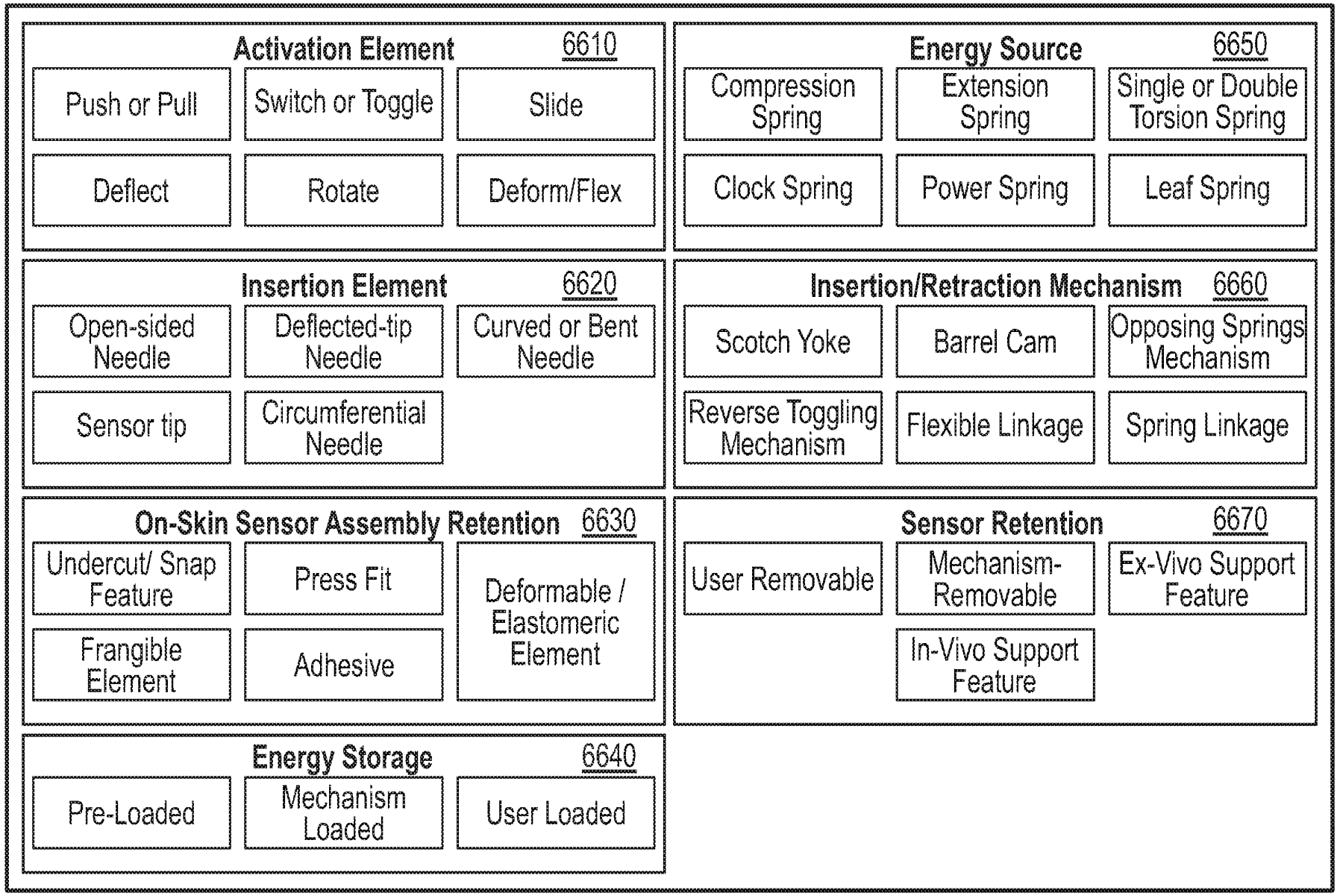

6500
6502
Provide an applicator comprising an applicator housing, a needle carrier assembly comprising an insertion element configured to insert a sensor of the on-skin assembly into the skin of the host, a holder releasably coupled to the needle carrier assembly and configured to hold the on-skin assembly while coupled to the needle carrier assembly, a drive assembly, and an activation element
6504
Activate the activation element, wherein activating the activation element causes the drive assembly to drive the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position, thereby inserting the sensor of the on-skin sensor assembly into the skin of the host

FIG. 65


Activation Element 6610
Push or Pull
Switch or Toggle
Slide
Deflect
Rotate
Deform/Flex
Energy Source 6650
Compression Spring
Extension Spring
Single or Double Torsion Spring
Clock Spring
Power Spring
Leaf Spring
Insertion Element 6620
Open-sided Needle
Deflected-tip Needle
Curved or Bent Needle
Sensor tip
Circumferential Needle
Insertion/Retraction Mechanism 6660
Scotch Yoke
Barrel Cam
Opposing Springs Mechanism
Reverse Toggling Mechanism
Flexible Linkage
Spring Linkage
On-Skin Sensor Assembly Retention 6630
Undercut/ Snap Feature
Press Fit
Deformable / Elastomeric Element
Frangible Element
Adhesive
Sensor Retention 6670
User Removable
Mechanism-Removable
Ex-Vivo Support Feature
In-Vivo Support Feature
Energy Storage 6640
Pre-Loaded
Mechanism Loaded
User Loaded

67/69

FIG. 66

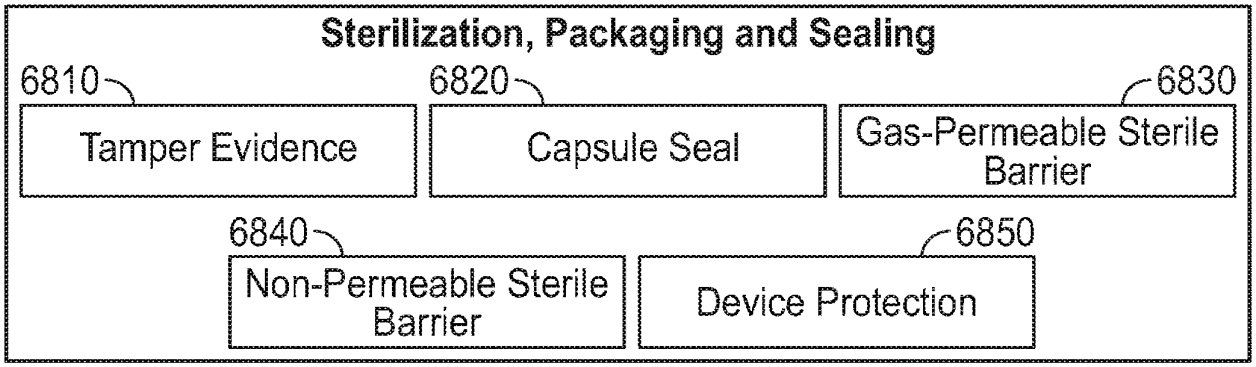

Sterilization, Packaging and Sealing
6810
Tamper Evidence
6820
Capsule Seal
6830
Gas-Permeable Sterile Barrier
6840
Non-Permeable Sterile Barrier
6850
Device Protection

FIG. 67

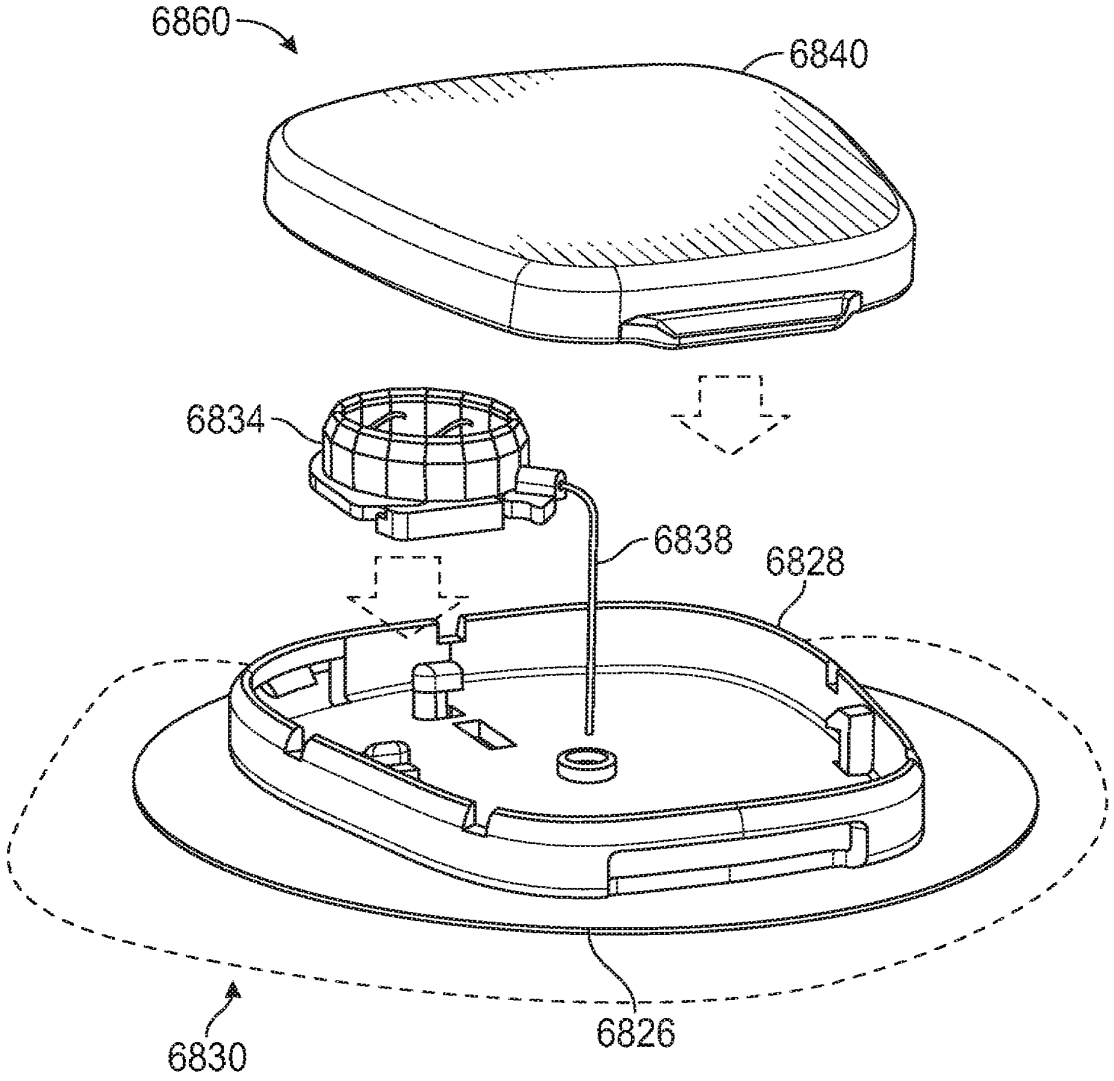

6860
6840
6834
6838
6828
6830
6826

FIG. 68

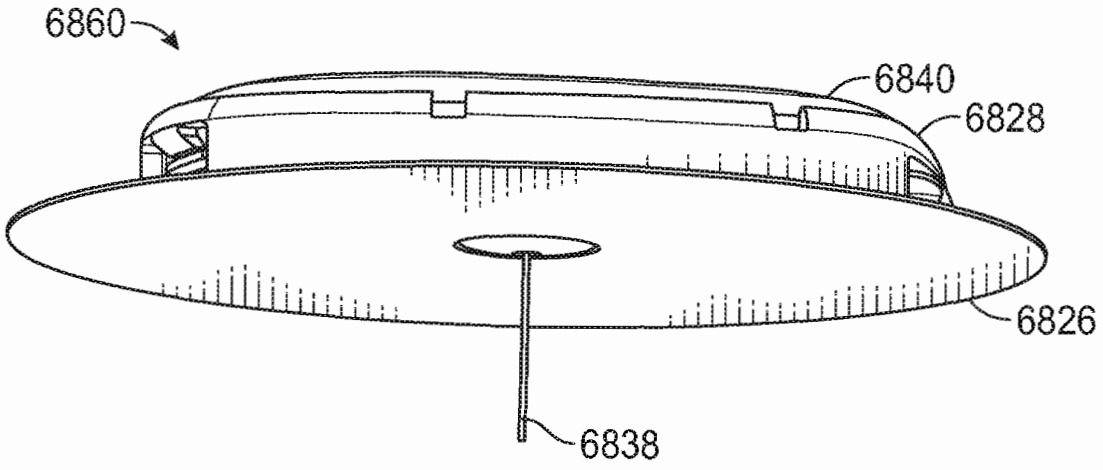


FIG. 69

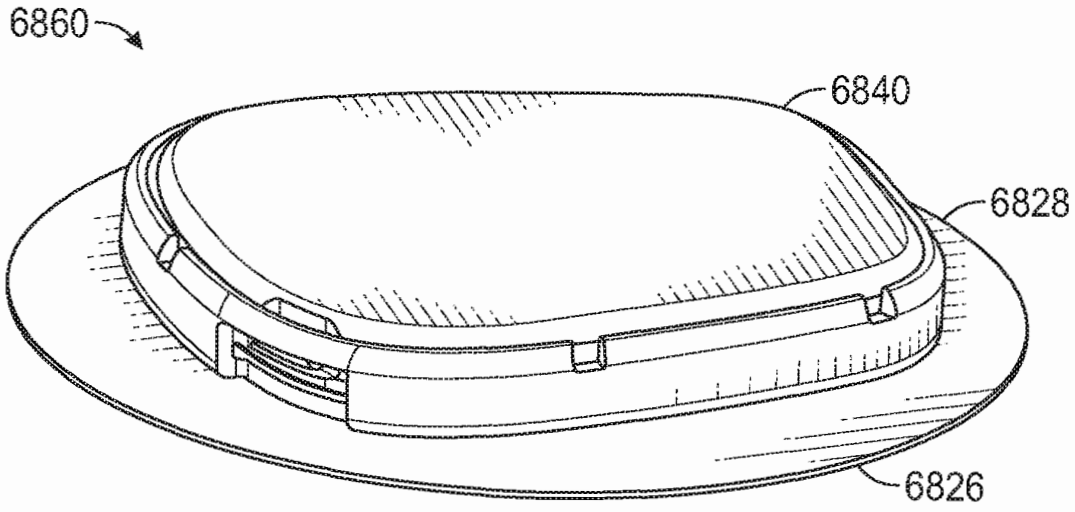


FIG. 70

TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS

FIELD

[0001] Systems and methods for measuring an analyte in a host are provided. More particularly, systems and methods are provided for applying a transcutaneous analyte measurement system to a host.

BACKGROUND

[0002] Diabetes mellitus is a disorder in which the pancreas cannot create sufficient insulin (Type I or insulin dependent) and/or in which insulin is not effective (Type 2 or non–insulin dependent). In the diabetic state, the victim suffers from high blood sugar, which can cause an array of physiological derangements associated with the deterioration of small blood vessels, for example, kidney failure, skin ulcers, or bleeding into the vitreous of the eye. A hypoglycemic reaction (low blood sugar) can be induced by an inadvertent overdose of insulin, or after a normal dose of insulin or glucose-lowering agent accompanied by extraordinary exercise or insufficient food intake.

[0003] Conventionally, a person with diabetes carries a self-monitoring blood glucose (SMBG) monitor, which typically requires uncomfortable finger pricking methods. Due to the lack of comfort and convenience, a person with diabetes normally only measures his or her glucose levels two to four times per day. Unfortunately, such time intervals are spread so far apart that the person with diabetes likely finds out too late of a hyperglycemic or hypoglycemic condition, sometimes incurring dangerous side effects. Glucose levels may be alternatively monitored continuously by a sensor system including an on-skin sensor assembly. The sensor system may have a wireless transmitter which transmits measurement data to a receiver which can process and display information based on the measurements.

[0004] The process of applying the sensor to the person is important for such a system to be effective and user friendly. The application process should result in the sensor assembly being attached to the person in a state where it is capable of sensing glucose level information, communicating the sensed data to the transmitter, and transmitting the glucose level information to the receiver.

[0005] This Background is provided to introduce a brief context for the Summary and Detailed Description that follow. This Background is not intended to be an aid in determining the scope of the claimed subject matter nor be viewed as limiting the claimed subject matter to implementations that solve any or all of the disadvantages or problems presented above.

SUMMARY

[0006] The present systems and methods relate to systems and methods for measuring an analyte in a host, and for applying a transcutaneous analyte measurement system to a host. The various embodiments of the present systems and methods for applying the analyte measurement system have several features, no single one of which is solely responsible for their desirable attributes. Without limiting the scope of the present embodiments as expressed by the claims that follow, their more prominent features now will be discussed briefly. After considering this discussion, and particularly after reading the section entitled "Detailed Description," one will understand how the features of the present embodiments provide the advantages described herein.

[0007] An applicator for applying an on-skin sensor assembly to a skin of a host is provided. The applicator includes an applicator housing, a needle carrier assembly, which includes an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host, a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly, and a drive assembly configured to drive the insertion element from a proximal starting position to a distal insertion position, and from the distal insertion position to a proximal retraction position.

[0008] In some embodiments, the on-skin sensor assembly includes an electronics unit. In some embodiments, the sensor is connected to the electronics unit in the applicator housing. In some embodiments, the holder is configured to release the on-skin sensor assembly after the sensor is inserted at least partially into the skin of the host. In some embodiments, the applicator further includes an activation element configured to activate the drive assembly. In some embodiments, the activation element includes a deflectable feature. In some embodiments, the deflectable feature is configured to provide resistance to activation. In some embodiments, the deflectable feature is configured to return the activation element to a starting positon. In some embodiments, the activation element includes one of a button, a switch, a toggle, a slide, a

trigger, and a knob. In some embodiments, the applicator further includes a safety element configured to prevent operation of the activation element. In some embodiments, the safety element includes a tab coupled to the activation element by at least one frangible member. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element. In some embodiments, the holder includes an elastomer.

[0009] In a first aspect, the applicator housing includes a guide. The drive assembly includes a rotating drive element coupled to the needle carrier assembly and includes a pin configured to travel in the guide during rotation of the rotating drive element, and a spring configured to, upon activation of the drive assembly, rotate the rotating drive element in a single rotational direction thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position. In some embodiments, the rotating drive element is configured to convert rotational motion into linear motion. In some embodiments, the rotating drive element includes a wheel cam. In some embodiments, the pin is radially offset from an axis of rotation of the rotating drive element. In some embodiments, the pin is positioned approximately 30 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the proximal starting position. In some embodiments, the pin is positioned approximately 180 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the distal insertion position. In some embodiments, the pin is positioned approximately 330 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the needle carrier assembly is in the proximal retracted position. In some embodiments, the pin travels in the guide in a direction perpendicular to a direction of extension of the insertion element. In some embodiments, the guide includes a slot. In some embodiments, the slot is stationary during sensor insertion. In some embodiments, the slot includes a horizontal slot. In some embodiments, the slot includes a vertical slot configured to receive at least the pin of the rotating drive element when loaded through a bottom of the applicator housing. In some embodiments, the applicator housing is stationary. In some embodiments, the rotating drive element further includes a protrusion in contact with a retention element configured to prevent the rotating drive element from rotating. In some embodiments, the applicator further includes an activation element configured to deflect the retention element, thereby allowing the rotating drive element to rotate. In some

embodiments, the rotating drive element further includes a protrusion configured to decouple the on-skin sensor assembly from the needle carrier assembly. In some embodiments, the protrusion is configured to apply a force to the on-skin sensor assembly during rotation of the rotating drive element. In some embodiments, the protrusion of the rotating drive element is configured to pass through a slot in the needle carrier assembly as the rotating drive element rotates.

[0010] In a second aspect, the drive assembly includes a torsion spring. The torsion spring includes a first end coupled to the applicator housing, and a second end coupled to the needle carrier assembly. Upon activation of the drive assembly, the first end and the second end unwind in opposite directions, thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position. In some embodiments, the first end and the second end unwinding in opposite directions drives the torsion spring in an arc. In some embodiments, the arc extends in a direction perpendicular to the distal direction and the proximal direction. In some embodiments, a spool coupled to the torsion spring. In some embodiments, the torsion spring is wrapped around the spool. In some embodiments, the second end of the torsion spring is configured to drive the insertion element. In some embodiments, the torsion spring is a double torsion spring. In some embodiments, the first end of the torsion spring is coupled to a protrusion of the applicator housing. In some embodiments, the second end of the torsion spring is coupled to a protrusion of the needle carrier assembly.

[0011] In a third aspect, the drive assembly further includes a linkage element, which includes a first end coupled to the first end of the torsion spring, a second end coupled to the second end of the torsion spring, and a hinge substantially aligned with a winding axis of the torsion spring. In some embodiments, the linkage element includes a flexible linkage.

[0012] In a fourth aspect, the drive assembly includes a linkage element, which includes a first end coupled to the applicator housing, a second end coupled to the needle carrier assembly, and a hinge disposed between the first end and the second end. The drive assembly further includes a torsion spring, which includes a first end coupled to the needle carrier assembly, and a second end coupled to the linkage element between the second end and the hinge. Upon activation of the drive assembly, the second end is configured to drive the linkage element such that the insertion element is driven from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retracted position.

[0013] In a fifth aspect, the drive assembly includes a linkage element, which includes a first end coupled to the applicator housing, a second end coupled to the needle carrier assembly, and a hinge disposed between the first end and the second end. The drive assembly further includes a torsion spring, which includes a first end coupled to the applicator housing, and a second end coupled to the linkage element between the first end and the hinge. Upon activation of the drive assembly, the second end is configured to drive the linkage element such that the insertion element is driven the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retracted position.

[0014] In a sixth aspect, the drive assembly includes a linkage element, which includes a first end coupled to the applicator housing, a second end coupled to the needle carrier assembly, and a hinge disposed between the first end and the second end. The drive assembly further includes an extension spring coupled to the linkage element. Upon activation of the drive assembly, the extension spring is configured to drive the linkage element such that the insertion element is driven in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position.

[0015] In a seventh aspect, the drive assembly includes a leaf spring, which includes a first end coupled to the applicator housing, and a second end coupled to the needle carrier assembly. Upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element at least in the distal direction to the distal insertion position.

[0016] In an eighth aspect, the drive assembly includes a linkage element, which includes a first end coupled to the applicator housing, a second end coupled to the needle carrier assembly, and a hinge disposed between the first end and the second end. The drive assembly further includes a leaf spring, which includes a first end coupled to the needle carrier assembly. and a second end coupled to the linkage element between the second end and the hinge. Upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position.

[0017] In a ninth aspect, the drive assembly includes a leaf spring, which includes a first end coupled to the applicator housing, and a second end coupled to the needle carrier assembly. Upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element at least in the distal direction to the distal insertion position.

[0018] In a tenth aspect, the drive assembly includes a linkage element, which includes a first end coupled to the applicator housing, a second end coupled to the needle carrier assembly; and a hinge disposed between the first end and the second end. The drive assembly further includes a leaf spring, which includes a first end coupled to the needle carrier assembly, and a second end coupled to the linkage element between the second end and the hinge. Upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position.

[0019] In an eleventh aspect, the drive assembly includes an insertion spring configured to, upon activation of the drive assembly, drive the insertion element in the distal direction to the distal insertion position, and a retraction spring in contact with the needle carrier assembly and configured to drive the insertion element from the distal insertion position to the proximal retracted position. In some embodiments, the insertion spring includes a compression spring. In some embodiments, the retraction spring includes a leaf spring. In some embodiments, the retraction spring is configured retract the insertion element from the skin of the host. In some embodiments, upon activation of the drive assembly, a portion of energy stored in the insertion spring is transferred to the retraction spring as the insertion spring drives the insertion element in the distal direction. In some embodiments, the insertion spring includes a first end coupled to the applicator housing and a second end coupled to the holder, and the holder is coupled to the needle carrier assembly while the insertion spring drives the insertion element in the distal direction to the distal insertion position and decoupled from the needle carrier assembly when the retraction spring drives the insertion element in the proximal direction from the distal insertion position. In some embodiments, the insertion element is configured to travel in an arc when driven in the distal direction and in the proximal direction.

[0020] In a twelfth aspect, the drive assembly includes a rotating drive element, which includes a ridge configured to slide along a channel in the needle carrier assembly, the ridge defining a variable cam path around at least a portion of a circumference of the rotating drive element, and a torsion spring configured to, upon activation of the drive assembly, rotate the rotating drive element thereby driving the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position based on the variable cam path. In some embodiments, the torsion spring is configured to, upon activation of

the drive assembly, rotate the rotating drive element in a single direction through an angle of greater than zero degrees and less than 360 degrees. In some embodiments, the rotating drive element includes a barrel cam. In some embodiments, the rotating drive element is configured to rotate in a plane substantially perpendicular to the proximal direction and the distal direction.

[0021] In a thirteenth aspect, the drive assembly includes a guide member coupled to the applicator housing, a hub configured to slide along the guide member, the hub in contact with a reverse toggling element through a first portion of travel along the guide member and in contact with the needle carrier assembly through a second portion of travel along the guide member. The reverse toggling element includes a fulcrum, a first end in contact with the hub through the first portion of travel along the guide member, and a second end coupled with the needle carrier assembly. The drive assembly further includes a spring configured to, upon activation of the drive assembly drive the hub in a proximal direction through the first portion of travel along the guide member, thereby driving the insertion element in the distal direction to the distal insertion position, and drive the hub in the proximal direction through the second portion of travel along the guide member, thereby driving the insertion element in the proximal direction from the distal insertion position.

[0022] In a fourteenth aspect, the drive assembly includes a first spring configured to, upon activation of the drive assembly, drive the needle carrier assembly in the distal direction to a distal insertion position, and a second spring configured to drive the needle carrier assembly in the proximal direction from the distal insertion position. In some embodiments, the first spring and the second spring are precompressed before activation of the drive assembly. In some embodiments, at least a portion of energy stored in the first spring is transferred to the second spring as the needle carrier assembly is driven in the distal direction to the distal insertion position.

[0023] In some embodiments, the holder includes at least one retention element configured to immobilize the holder to the applicator housing upon the needle carrier assembly reaching the distal insertion position. In some embodiments, the holder further includes a retention element configured to releasably couple the on-skin sensor assembly to the holder as the needle carrier assembly travels in the distal direction to the distal insertion position, and decouple the on-skin sensor assembly from the holder as the needle carrier assembly travels in the proximal direction from the distal insertion position.

[0024] In some embodiments, the holder includes a retention element, which includes a first end and a second end. The first end is immobilized in a guide of the needle carrier assembly thereby releasably coupling the second end to the on-skin sensor assembly as the needle carrier assembly travels in the distal direction to the distal insertion position, and the first end is unseated from the guide of the needle carrier assembly thereby decoupling the second end from the on-skin sensor assembly as the needle carrier assembly travels in the proximal direction from the distal insertion position and separates from the holder.

[0025] In some embodiments, the needle carrier assembly includes a retention element releasably coupling the on-skin sensor assembly to the holder as the needle carrier assembly travels in the distal direction to the distal insertion position, and the retention element is configured to deform sufficiently to decouple from the on-skin sensor assembly as the needle carrier assembly travels in the proximal direction from the distal insertion position and separates from the holder.

[0026] In some embodiments, the holder includes a deformable retention element releasably coupling the on-skin sensor assembly to the holder, the needle carrier assembly in contact with the deformable retention element thereby preventing the deformable retention element from deforming as the needle carrier assembly travels in the distal direction to the distal insertion position. The needle carrier assembly separates from the holder as the needle carrier assembly travels in the proximal direction from the distal insertion position thereby allowing the retention element to deform sufficiently to decouple from the on-skin sensor assembly.

[0027] In some embodiments, the needle carrier assembly includes a first retention element configured to releasably couple the holder to the needle carrier assembly, and a second retention element configured to releasably couple the on-skin sensor assembly to one of the holder and the needle carrier assembly.

[0028] In some embodiments, the insertion element includes a C-needle having flared edges. In some embodiments, the insertion element includes a deflected-tip needle. In some embodiments, the insertion element includes a needle having a curvilinear profile configured to substantially track a path of insertion of the needle. In some embodiments, the insertion element includes a needle and the needle carrier assembly further includes a needle hub configured as a pass through for the needle during insertion of the sensor and is further configured to enclose a

tip of the needle after insertion of the sensor. The insertion element further includes a needle spring configured to drive the needle hub to the tip of the needle after insertion of the sensor.

[0029] In some embodiments, the on-skin sensor assembly includes a fill port configured to receive a fluid or gel and a cannula configured to deliver the fluid or gel through the skin of the host.

[0030] In some embodiments, the applicator further includes an elastomeric sensor retention element coupled to the applicator housing at a first end and coupled to at least one of the insertion element and the sensor. The elastomeric sensor retention element is configured to retain the sensor within the insertion element prior to activation of the drive assembly. In some embodiments upon activation, the insertion element is configured to progress in the proximal direction such that the elastomeric sensor retention element decouples from the at least one of the insertion element and the sensor.

[0031] In some embodiments, the applicator further includes a sensor retention element, which includes a tab configured to retain the sensor within the insertion element prior to activation of the drive assembly.

[0032] In some embodiments, the applicator further includes a sensor retention element disposed against at least one of the insertion element and the sensor in a first position and configured to rotate away from the insertion element and the sensor in a second position.

[0033] In some embodiments, the applicator further includes a sensor retention sleeve disposed around at least a portion of the insertion element and the sensor. The needle carrier assembly includes a tapered needle hub configured to split the sensor retention sleeve during insertion of the sensor.

[0034] In some embodiments, the sensor includes a strain relief feature configured to limit the sensor from bending at a bend radius smaller than a predetermined bend radius. In some embodiments, the strain relief feature includes an elastomeric material.

[0035] In some embodiments, the on-skin sensor assembly includes an open cavity configured to receive the sensor and provide an area for the sensor to bend from extending in a substantially horizontal direction to extending in a substantially vertical direction. In some embodiments, the open cavity is configured to guide bodily fluid released from the host as a result of insertion of the sensor at least partially into the skin of the host. In some embodiments,

the on-skin assembly includes a wicking material configured to absorb a bodily fluid released from the host as a result of insertion of the sensor at least partially into the skin of the host.

[0036] In a fifteenth aspect, a method for applying an on-skin sensor assembly to skin of a host is provided. The method includes providing an applicator, which includes an applicator housing, a needle carrier assembly includes an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host, a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly and a drive assembly and an activation element. The method includes activating the activation element, wherein activating the activation element causes the drive assembly to drive the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position, thereby inserting the sensor of the on-skin sensor assembly at least partially into the skin of the host. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element.

[0037] In some embodiments, the applicator housing includes a guide. The drive assembly includes a rotating drive element coupled to the needle carrier assembly and includes a pin configured to travel in the guide during rotation of the rotating drive element, and a spring configured to, upon activation of the drive assembly, rotate the rotating drive element in a single rotational direction thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position. In some embodiments, the rotating drive element is configured to convert rotational motion into linear motion. In some embodiments, the rotating drive element includes a wheel cam. In some embodiments, the pin is radially offset from an axis of rotation of the rotating drive element. In some embodiments, the pin is positioned approximately 30 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the proximal starting position. In some embodiments, the pin is positioned approximately 180 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the distal insertion position. In some embodiments, the pin is positioned approximately 330 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the needle carrier assembly is in the proximal retracted position. In some embodiments, the guide includes a slot.

[0038] In some embodiments, the drive assembly includes a torsion spring, the torsion spring includes a first end coupled to the applicator housing, and a second end coupled to the needle carrier assembly. Upon activation of the drive assembly, the first end and the second end unwind in opposite directions, thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position. In some embodiments, the first end and the second end unwinding in opposite directions drives the torsion spring in an arc. In some embodiments, the arc extends in a direction perpendicular to the distal direction and the proximal direction.

[0039] In some embodiments, the drive assembly includes an insertion spring configured to, upon activation of the drive assembly, drive the insertion element in the distal direction to the distal insertion position, and a retraction spring in contact with the needle carrier assembly and configured to drive the insertion element from the distal insertion position to the proximal retracted position. In some embodiments, the insertion spring includes a compression spring. In some embodiments, the retraction spring includes a leaf spring. In some embodiments, upon activation of the drive assembly, a portion of energy stored in the insertion spring is transferred to the retraction spring as the insertion spring drives the insertion element in the distal direction. In some embodiments, the insertion spring includes a first end coupled to the applicator housing and a second end coupled to the holder. The holder is coupled to the needle carrier assembly while the insertion spring drives the insertion element in the distal direction to the distal insertion position and decoupled from the needle carrier assembly when the retraction spring drives the insertion element in the proximal direction from the distal insertion position. In some embodiments, the insertion element is configured to travel in an arc when driven in the distal direction and in the proximal direction.

[0040] In some embodiments, the drive assembly includes a rotating drive element, which includes a ridge configured to slide along a channel in the needle carrier assembly, the ridge defining a variable cam path around at least a portion of a circumference of the rotating drive element, and a torsion spring configured to, upon activation of the drive assembly, rotate the rotating drive element thereby driving the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position based on the variable cam path. In some embodiments, the torsion spring is configured to, upon activation of the drive assembly, rotate the rotating drive element in a single direction through an angle of

greater than zero degrees and less than 360 degrees. In some embodiments, the rotating drive element includes a barrel cam. In some embodiments, the rotating drive element is configured to rotate in a plane substantially perpendicular to the proximal direction and the distal direction.

[0041] In some embodiments, the drive assembly includes a guide member coupled to the applicator housing, a hub configured to slide along the guide member, the hub in contact with a reverse toggling element through a first portion of travel along the guide member and in contact with the needle carrier assembly through a second portion of travel along the guide member. The reverse toggling element includes a fulcrum, a first end in contact with the hub through the first portion of travel along the guide member, and a second end coupled with the needle carrier assembly; The drive assembly further includes a spring configured to, upon activation of the drive assembly, drive the hub in a proximal direction through the first portion of travel along the guide member, thereby driving the insertion element in the distal direction to the distal insertion position, and drive the hub in the proximal direction through the second portion of travel along the guide member, thereby driving the insertion element in the proximal direction from the distal insertion position.

[0042] In some embodiments, the drive assembly includes a first spring configured to, upon activation of the drive assembly, drive the needle carrier assembly in the distal direction to a distal insertion position, and a second spring configured to drive the needle carrier assembly in the proximal direction from the distal insertion position. In some embodiments, at least a portion of energy stored in the first spring is transferred to the second spring as the needle carrier assembly is driven in the distal direction to the distal insertion position.

[0043] This Summary is provided to introduce a selection of concepts further described in the Detailed Description section. Elements or steps other than those described in this Summary are possible, and no element or step is necessarily required. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended for use as an aid in determining the scope of the claimed subject matter. The claimed subject matter is not limited to implementations that solve any or all disadvantages noted in any part of this disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0044] These and other features, aspects, and advantages are described below with reference to the drawings, which are intended to illustrate, but not to limit, the invention. In the drawings, like reference characters denote corresponding features consistently throughout similar embodiments.

[0045] **FIG. 1** illustrates a schematic view of a continuous analyte sensor system, according to some embodiments.

[0046] **FIGs. 2A-2B** illustrate perspective views of an on-skin sensor assembly, according to some embodiments.

[0047] **FIGs. 3A-3B** illustrate perspective views of another on-skin sensor assembly, according to some embodiments.

[0048] **FIG. 4** illustrates a cross-sectional view of the on-skin sensor assembly of **FIGs. 3A-3B**, according to some embodiments.

[0049] **FIG. 5** illustrates an exploded perspective view of the applicator of **FIG. 5**, according to some embodiments.

[0050] **FIG. 6A-6H** illustrate cutaway views and perspective views of several features of the applicator of **FIG. 5**, according to some embodiments.

[0051] **FIGs. 7A-7F** illustrate several cutaway views of the applicator of **FIG. 5** during operation, according to some embodiments.

[0052] **FIG. 8** illustrates a cutaway view of an applicator similar to the applicator of **FIG. 5**, however, including an activation element on an upper side of an applicator housing, according to some embodiments.

[0053] **FIG. 9** illustrates a cutaway view of an applicator similar to the applicator of **FIG. 5**, however, including an activation element on a medial side of an applicator housing, according to some embodiments.

[0054] **FIG. 10** illustrates a cutaway view of an applicator similar to the applicator of **FIG. 5**, however, including an activation element on a lower side of an applicator housing, according to some embodiments.

[0055] **FIGs. 11A-11D** and **11J** illustrate perspective views while **FIGs. 11E-11H** illustrate side cutaway views of steps for assembling the applicator of **FIG. 5**, according to some embodiments.

[0056] **FIG. 12** illustrates an exploded perspective view of another applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0057] **FIG. 13A-13F** illustrate perspective views and cutaway views of several features of the applicator of **FIG. 12**, according to some embodiments.

[0058] **FIGs. 14A-14E** illustrate several cross-sectional views of the applicator of **FIG. 12** during operation, according to some embodiments.

[0059] **FIG. 15** illustrates a perspective view of an exemplary double torsional spring for use in an applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0060] **FIG. 16** illustrates a perspective view of another exemplary double torsional spring for use in an applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0061] **FIG. 17** illustrates a perspective view of yet another exemplary double torsional spring for use in an applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0062] **FIG. 18** illustrates a cutaway view of an alternative driving mechanism including a torsional spring and a living hinge for the applicator of **FIG. 12**, according to some embodiments.

[0063] **FIG. 19** illustrates a cutaway view of another alternative driving mechanism including a torsional spring and a living hinge for the applicator of **FIG. 12**, according to some embodiments.

[0064] **FIG. 20** illustrates a cutaway view of yet another alternative driving mechanism including a torsional spring and a living hinge for the applicator of **FIG. 12**, according to some embodiments.

[0065] **FIG. 21** illustrates a cutaway view of yet another alternative driving mechanism including an extension spring and a living hinge for the applicator of **FIG. 12**, according to some embodiments.

[0066] **FIG. 22** illustrates a cutaway view of yet another alternative driving mechanism including a leaf spring for the applicator of **FIG. 12**, according to some embodiments.

[0067] **FIG. 23** illustrates a cutaway view of yet another alternative driving mechanism including a leaf spring and a living hinge for the applicator of **FIG. 12**, according to some embodiments.

[0068] **FIGs. 24A-24F, 24H-24J and 24L-24M** illustrate cross-sectional views while **FIGs. 24G** and **24K** illustrate perspective views of steps for assembling the applicator of **FIG. 12**, according to some embodiments.

[0069] **FIG. 25** illustrates an exploded perspective view of yet another applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0070] **FIG. 26A-26D** illustrate several cutaway perspective views and a bottom view of several features of the applicator of **FIG. 25**, according to some embodiments.

[0071] **FIGs. 27A-27E** illustrate several cross-sectional views of the applicator of **FIG. 25** during operation, according to some embodiments.

[0072] **FIGs. 28A-28C** and **28H** illustrate several perspective views while **FIGs. 28D-28G** illustrate cross-sectional views of assembling the applicator of **FIG. 25**, according to some embodiments.

[0073] **FIG. 29** illustrates an exploded perspective view of an applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0074] **FIG. 30** illustrates a cutaway view of a portion of the applicator of **FIG. 29**, according to some embodiments.

[0075] **FIG. 31** illustrates a cutaway view of yet another applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0076] **FIGs. 32A-34B** illustrate exploded perspective views of yet another applicator for an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0077] **FIGs. 33A-33E** illustrate several perspective cutaway views of several features of the applicator of **FIG. 32**, according to some embodiments.

[0078] **FIG. 34A-34D** illustrate several cross-sectional views of the applicator of **FIG. 32** during operation, according to some embodiments.

[0079] **FIG. 35A-35C** illustrate cross-sectional views of an on-skin sensor assembly retention mechanism of the applicator of **FIG. 32**, according to some embodiments.

[0080] **FIG. 36A-36C** illustrate cross-sectional views of another on-skin sensor assembly retention mechanism of the applicator of **FIG. 32**, according to some embodiments.

[0081] **FIG. 37A-37C** illustrate cross-sectional views of yet another on-skin sensor assembly retention mechanism of the applicator of **FIG. 32**, according to some embodiments.

[0082] **FIG. 38** illustrates a perspective view of an applicator similar to those shown in **FIG. 32**, including an activation element on a side of the housing, according to some embodiments.

[0083] **FIG. 39** illustrates a cutaway perspective view of a portion of the applicator of **FIG.** 38, according to some embodiments.

[0084] **FIGs. 40A-40G** illustrate several perspective views of steps for assembling the applicator of **FIG. 32**, according to some embodiments.

[0085] **FIGs. 41A-41B** illustrate cross-sectional views an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0086] **FIGs. 42A-42B** illustrate cross-sectional views of another exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0087] **FIGs. 43A-43B** illustrate cross-sectional views of yet another exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0088] **FIG. 44** illustrates a perspective view of a portion of another exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0089] **FIG. 45** illustrates a perspective view of portion of an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0090] **FIG. 46** illustrates a perspective view of a portion of an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments.

[0091] **FIG. 47** illustrates a cross-section of a kinked needle for use in an applicator for an analyte sensor system, according to some embodiments.

[0092] **FIGs. 48A-48B** illustrate a cross-section and a plan view, respectively, of a flared C-needle for use in an applicator for an analyte sensor system, according to some embodiments.

[0093] **FIG. 49** illustrates a perspective view of a deflected-tip needle for use in an applicator for an analyte sensor system, according to some embodiments.

[0094] **FIG. 50** illustrates a perspective view of a curved needle for use in an applicator for an analyte sensor system, according to some embodiments.

[0095] **FIGs. 51A-51B** illustrate cutaway views of a needle hub of an applicator for an analyte sensor system, according to some embodiments.

[0096] **FIGs. 52A-52B** illustrate a cross-sectional view and a plan view, respectively, of an infusion cannula integrated into an on-skin sensor assembly of an analyte sensor system, according to some embodiments.

[0097] **FIG. 53** illustrates a cross-sectional view of a sensor retention mechanism for an applicator for an analyte sensor system, according to some embodiments.

[0098] **FIG. 54** illustrates a perspective view of another sensor retention mechanism for an applicator for an analyte sensor system, according to some embodiments.

[0099] **FIG. 55** illustrates a cutaway view of another sensor retention mechanism for an applicator for an analyte sensor system, according to some embodiments.

[0100] **FIGs. 56A-56B** illustrate perspective views of another sensor retention element for an applicator for an analyte sensor system, according to some embodiments.

[0101] **FIG. 57** illustrates a cross-sectional view of yet another sensor retention element for an applicator for an analyte sensor system, according to some embodiments.

[0102] **FIG. 58** illustrates a cross-sectional view of yet another sensor retention element for an applicator for an analyte sensor system, according to some embodiments.

[0103] **FIGs. 59A-59B** illustrate cross-sectional views of yet another sensor retention element for an applicator for an analyte sensor system, according to some embodiments.

[0104] **FIG. 60** illustrates a cutaway view of an on-skin assembly having at least a portion of a sensor potted in a flexible material, according to some embodiments.

[0105] **FIG. 61** illustrates a cutaway view of an on-skin assembly comprising an open cavity configured to allow a larger bend radius in a sensor, according to some embodiments.

[0106] **FIG. 62** illustrates a cutaway view of an on-skin assembly comprising an open cavity configured to allow a larger bend radius in a sensor, according to some embodiments.

[0107] **FIG. 63** illustrates a cutaway view of an on-skin assembly comprising an open cavity configured to allow a larger bend radius in a sensor, according to some embodiments.

[0108] **FIGs. 64A-64B** illustrate a battery engagement feature for an on-skin sensor assembly, according to some embodiments.

[0109] **FIG. 65** illustrates a flowchart of a method for applying an on-skin sensor assembly to skin of a host, according to some embodiments.

[0110] **FIG. 66** illustrates exemplary mechanisms for several features of an applicator configured to apply an on-skin sensor assembly to skin of a host, according to some embodiments.

[0111] **FIG. 67** illustrates exemplary sterilization, packaging and sealing features of an applicator configured to apply an on-skin sensor assembly to skin of a host, according to some embodiments.

[0112] **FIG. 68** illustrates a top perspective view of an on-skin sensor assembly, according to some embodiments.

[0113] **FIG. 69** illustrates a bottom perspective view of the on-skin sensor assembly of **FIG. 68**, according to some embodiments.

[0114] **FIG. 70** illustrates a cross-sectional view of the on-skin sensor assembly of **FIG. 68**, according to some embodiments.

DETAILED DESCRIPTION

[0115] The following description and examples illustrate some example embodiments in detail. Those of skill in the art will recognize that there are numerous variations and modifications of this disclosure encompassed by its scope. Accordingly, the description of a certain example embodiment should not be deemed to limit the scope of the present disclosure.

System Introduction

[0116] **FIG. 1** is a diagram depicting an example continuous analyte monitoring system 100 including an analyte sensor system 102 comprising an on-skin sensor assembly 160 configured to be fastened to the skin of a host via a base (not shown). Analyte sensor system 102 is operatively connected to a host and a plurality of display devices 110-114 according to certain aspects of the present disclosure. Example display devices 110-114 may include computers such as smartphones, smartwatches, tablet computers, laptop computers, and desktop computers. In some embodiments, display devices 110-114 may be Apple Watches, iPhones, and iPads made

by Apple Inc., or Windows or Google devices. It should be noted that display device 114 alternatively or in addition to being a display device, may be a medicament delivery device that can act cooperatively with analyte sensor system 102 to deliver medicaments to the host. Analyte sensor system 102 may include a sensor electronics module 140 and a continuous analyte sensor 138 associated with sensor electronics module 140. Sensor electronics module 140 may be in direct wireless communication with one or more of the plurality of display devices 110-114 via wireless communications signals. As will be discussed in greater detail below, display devices 110-114 may also communicate amongst each other and/or through each other to analyte sensor system 102. For ease of reference, wireless communications signals from analyte sensor system 102 to display devices 110-114 can be referred to as "uplink" signals 128. Wireless communications signals from, e.g., display devices 110-114 to analyte sensor system 102 can be referred to as "downlink" signals 130. Wireless communication signals between two or more of display devices 110-114 may be referred to as "crosslink" signals 132. Additionally, wireless communication signals can include data transmitted by one or more of display devices 110-113 via "long-range" uplink signals 136 (e.g., cellular signals) to one or more remote servers 190 or network entities, such as cloud-based servers or databases, and receive long-range downlink signals 142 transmitted by remote servers 190.

[0117] In embodiments shown by **FIG. 1**, one of the plurality of display devices may be a custom display device 111 specially designed for displaying certain types of displayable sensor information associated with analyte values received from the sensor electronics module 126 (e.g., a numerical value and an arrow, in some embodiments). In some embodiments, one of the plurality of display devices may be a handheld device 112, such as a mobile phone based on the Android, iOS operating system or other operating system, a palm-top computer and the like, where handheld device 112 may have a relatively larger display and be configured to display a graphical representation of the continuous sensor data (e.g., including current and historic data). Other display devices can include other hand-held devices, such as a tablet 113, a smart watch 110, a medicament delivery device 114, a blood glucose meter, and/or a desktop or laptop computer.

[0118] It should be understood that in the case of display device 134e, which may be a medicament delivery device in addition to or instead of a display device, the alerts and/or sensor

information provided by continuous analyte sensor 122 vis-à-vis sensor electronics module 126, can be used to initiate and/or regulate the delivery of the medicament to host 120.

[0119] During use, a sensing portion of sensor 138 may be disposed under the host's skin and a contact portion of sensor 138 can be electrically connected to electronics unit 140. Electronics unit 140 can be engaged with a housing (e.g., a base) which is attached to an adhesive patch fastened to the skin of the host. In some embodiments, electronics unit 140 is integrally formed with the housing. Furthermore, electronics unit 140 may be disposable and directly coupled to the adhesive patch.

[0120] Continuous analyte sensor system 100 can include a sensor configuration that provides an output signal indicative of a concentration of an analyte. The output signal including (e.g., sensor data, such as a raw data stream, filtered data, smoothed data, and/or otherwise transformed sensor data) is sent to the receiver.

[0121] In some embodiments, analyte sensor system 100 includes a transcutaneous glucose sensor, such as is described in U.S. Patent Publication No. US-2011-0027127-A1, the entire contents of which are hereby incorporated by reference. In some embodiments, sensor system 100 includes a continuous glucose sensor and comprises a transcutaneous sensor (e.g., as described in U.S. Pat. No. 6,565,509, as described in U.S. Pat. No. 6,579,690, and/or as described in U.S. Pat. No. 6,484,046). The contents of U.S. Pat. No. 6,565,509, U.S. Pat. No. 6,579,690, and U.S. Pat. No. 6,484,046 are hereby incorporated by reference in their entirety.

[0122] Various signal processing techniques and glucose monitoring system embodiments suitable for use with the embodiments described herein are described in U.S. Patent Publication No. US-2005-0203360-A1 and U.S. Patent Publication No. US-2009-0192745-A1, the contents of which are hereby incorporated by reference in their entirety. The sensor can extend through a housing, which can maintain sensor 138 on, in or under the skin and/or can provide for electrical connection of sensor 138 to sensor electronics in electronics unit 140.

[0123] In some embodiments, description of a base, a housing, a wearable, and/or a transmitter of on-skin sensor assembly 160 may be interchangeable. In other embodiments, a base and a housing of on-skin sensor assembly 160 may be different in the sense that they may be separate components from sensor electronics module 140, e.g., from a transmitter or receiver.

[0124] In several embodiments, sensor 138 is in a form of a wire. A distal end of the wire can be formed, e.g., having a conical shape (to facilitate inserting the wire into the tissue of the host). Sensor 138 can include an elongated conductive body, such as an elongated conductive core (e.g., a metal wire) or an elongated conductive core coated with one, two, three, four, five, or more layers of material, each of which may or may not be conductive. The elongated sensor may be long and thin, yet flexible and strong. For example, in some embodiments, the smallest dimension of the elongated conductive body is less than 0.1 inches, less than 0.075 inches, less than 0.05 inches, less than 0.025 inches, less than 0.01 inches, less than 0.004 inches, less than 0.002 inches, less than 0.001 inches, and/or less than 0.0005 inches.

[0125] Sensor 138 may have a circular cross section. In some embodiments, the cross section of the elongated conductive body can be ovoid, rectangular, triangular, polyhedral, star-shaped, C-shaped, T-shaped, X-shaped, Y-shaped, irregular, or the like. In some embodiments, a conductive wire electrode is employed as a core. In other embodiments, sensor 138 may be disposed on a substantially planar substrate. To such an electrode, one or two additional conducting layers may be added (e.g., with intervening insulating layers provided for electrical isolation). The conductive layers can be comprised of any suitable material. In certain embodiments, it may be desirable to employ a conductive layer comprising conductive particles (i.e., particles of a conductive material) in a polymer or other binder.

[0126] In some embodiments, the materials used to form the elongated conductive body (e.g., stainless steel, titanium, tantalum, platinum, platinum-iridium, iridium, certain polymers, and/or the like) can be strong and hard, and therefore can be resistant to breakage. For example, in several embodiments, the ultimate tensile strength of the elongated conductive body is greater than 80 kPsi and less than 140 kPsi, and/or the Young's modulus of the elongated conductive body is greater than 160 GPa and less than 220 GPa. The yield strength of the elongated conductive body can be greater than 58 kPsi and less than 2200 kPsi.

[0127] Electronics unit 140 can be releasably or permanently coupled to sensor 138. Electronics unit 140 can include electronic circuitry associated with measuring and processing the continuous analyte sensor data. Electronics unit 140 can be configured to perform algorithms associated with processing and calibration of the sensor data. For example, electronics unit 140 can provide various aspects of the functionality of a sensor electronics module as described in U.S. Patent Publication No. US-2009-0240120-A1 and U.S. Patent Publication No. US-2012-

0078071-A1, the entire contents of which are incorporated by reference herein. Electronics unit 140 may include hardware, firmware, and/or software that enable measurement of levels of the analyte via a glucose sensor, such as sensor 138.

[0128] For example, electronics unit 140 can include a potentiostat, a power source for providing power to sensor 138, signal processing components, data storage components, and a communication module (e.g., a telemetry module) for one-way or two-way data communication between electronics unit 140 and one or more receivers, repeaters, and/or display devices, such as devices 110-114. Electronic components can be affixed to a printed circuit board (PCB), or the like, and can take a variety of forms. The electronic components can take the form of an integrated circuit (IC), such as an Application-Specific Integrated Circuit (ASIC), a microcontroller, and/or a processor. The electronics unit 140 may include sensor electronics that are configured to process sensor information, such as storing data, analyzing data streams, calibrating analyte sensor data, estimating analyte values, comparing estimated analyte values with time-corresponding measured analyte values, analyzing a variation of estimated analyte values, and the like. Examples of systems and methods for processing sensor analyte data are described in more detail in U.S. Pat. No. 7,310,544, U.S. Pat. No. 6,931,327, U.S. Patent Publication No. 1205-0043598-A1, U.S. Patent Publication No. 1207-0032706-A1, U.S. Patent Publication No. 1207-0016381-A1, U.S. Patent Publication No. 1208-0033254-A1, U.S. Patent Publication No. 1205-0203360-A1, U.S. Patent Publication No. 1205-0154271-A1, U.S. Patent Publication No. 1205-0192557-A1, U.S. Patent Publication No. 1206-0222566-A1, U.S. Patent Publication No. 1207-0203966-A1 and U.S. Patent Publication No. 1207-0208245-A1, the contents of which are hereby incorporated by reference in their entirety. Electronics unit 140 may communicate with the devices 110-114, and/or any number of additional devices, via any suitable communication protocol. Example communication methods or protocols include radio frequency; Bluetooth; universal serial bus; any of the wireless local area network (WLAN) communication standards, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols; ZigBee; wireless (e.g., cellular) telecommunication; paging network communication; magnetic induction; satellite data communication; a proprietary communication protocol, open source communication protocol, and/or any suitable wireless communication method.

[0129] Additional sensor information is described in U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201. The entire contents of U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201 are incorporated by reference herein.

[0130] Any sensor shown or described herein can be an analyte sensor; a glucose sensor; and/or any other suitable sensor. A sensor described in the context of any embodiment can be any sensor described herein or incorporated by reference. Sensors shown or described herein can be configured to sense, measure, detect, and/or interact with any analyte.

[0131] As used herein, the term "analyte" is a broad term, and is to be given its ordinary and customary meaning to a person of ordinary skill in the art (and is not to be limited to a special or customized meaning), and refers without limitation to a substance or chemical constituent in a biological fluid (for example, blood, interstitial fluid, cerebral spinal fluid, lymph fluid, urine, sweat, saliva, etc.) that can be analyzed. Analytes can include naturally occurring substances, artificial substances, metabolites, or reaction products.

[0132] In some embodiments, the analyte for measurement by the sensing regions, devices, systems, and methods is glucose. However, other analytes are contemplated as well, including, but not limited to ketone bodies; Acetyl Co A; acarboxyprothrombin; acylcarnitine; adenine phosphoribosyl transferase; adenosine deaminase; albumin; alpha-fetoprotein; amino acid profiles (arginine (Krebs cycle), histidine/urocanic acid, homocysteine, phenylalanine/tyrosine, tryptophan); andrenostenedione; antipyrine; arabinitol enantiomers; arginase; benzoylecgonine (cocaine); biotinidase; biopterin; c-reactive protein; carnitine; carnosinase; CD4; ceruloplasmin; chenodeoxycholic acid; chloroquine; cholesterol; cholinesterase; cortisol; testosterone; choline; creatine kinase; creatine kinase MM isoenzyme; cyclosporin A; d-penicillamine; de-ethylchloroquine; dehydroepiandrosterone sulfate; DNA (acetylator polymorphism, alcohol dehydrogenase, alpha 1-antitrypsin, cystic fibrosis, Duchenne/Becker muscular dystrophy, glucose-6-phosphate dehydrogenase, hemoglobin A, hemoglobin S, hemoglobin C, hemoglobin D, hemoglobin E, hemoglobin F, D-Punjab, beta-thalassemia, hepatitis B virus, HCMV, HIV-1, HTLV-1, Leber hereditary optic neuropathy, MCAD, RNA, PKU, Plasmodium vivax, sexual differentiation, 21-deoxycortisol); desbutylhalofantrine; dihydropteridine reductase; diptheria/tetanus antitoxin; erythrocyte arginase; erythrocyte protoporphyrin; esterase D; fatty acids/acylglycines; triglycerides; glycerol; free ß-human chorionic gonadotropin; free erythrocyte porphyrin; free thyroxine (FT4); free tri-

iodothyronine (FT3); fumarylacetoacetase; galactose/gal-1-phosphate; galactose-1-phosphate uridyltransferase; gentamicin; glucose-6-phosphate dehydrogenase; glutathione; glutathione perioxidase; glycocholic acid; glycosylated hemoglobin; halofantrine; hemoglobin variants; hexosaminidase A; human erythrocyte carbonic anhydrase I; 17-alpha-hydroxyprogesterone; hypoxanthine phosphoribosyl transferase; immunoreactive trypsin; lactate; lead; lipoproteins ((a), B/A-1, ß); lysozyme; mefloquine; netilmicin; phenobarbitone; phenytoin; phytanic/pristanic acid; progesterone; prolactin; prolidase; purine nucleoside phosphorylase; quinine; reverse tri-iodothyronine (rT3); selenium; serum pancreatic lipase; sissomicin; somatomedin C; specific antibodies (adenovirus, anti-nuclear antibody, anti-zeta antibody, arbovirus, Aujeszky's disease virus, dengue virus, Dracunculus medinensis, Echinococcus granulosus, Entamoeba histolytica, enterovirus, Giardia duodenalisa, Helicobacter pylori, hepatitis B virus, herpes virus, HIV-1, IgE (atopic disease), influenza virus, Leishmania donovani, leptospira, measles/mumps/rubella, Mycobacterium leprae, Mycoplasma pneumoniae, Myoglobin, Onchocerca volvulus, parainfluenza virus, Plasmodium falciparum, poliovirus, Pseudomonas aeruginosa, respiratory syncytial virus, rickettsia (scrub typhus), Schistosoma mansoni, Toxoplasma gondii, Trepenoma pallidium, Trypanosoma cruzi/rangeli, vesicular stomatis virus, Wuchereria bancrofti, yellow fever virus); specific antigens (hepatitis B virus, HIV-1); acetone (e.g., succinylacetone); acetoacetic acid; sulfadoxine; theophylline; thyrotropin (TSH); thyroxine (T4); thyroxine-binding globulin; trace elements; transferrin; UDP-galactose-4-epimerase; urea; uroporphyrinogen I synthase; vitamin A; white blood cells; and zinc protoporphyrin.

[0133] Salts, sugar, protein, fat, vitamins, and hormones naturally occurring in blood or interstitial fluids can also constitute analytes in certain embodiments. The analyte can be naturally present in the biological fluid or endogenous, for example, a metabolic product, a hormone, an antigen, an antibody, and the like. Alternatively, the analyte can be introduced into the body or exogenous, for example, a contrast agent for imaging, a radioisotope, a chemical agent, a fluorocarbon-based synthetic blood, or a drug or pharmaceutical composition, including but not limited to insulin; glucagon; ethanol; cannabis (marijuana, tetrahydrocannabinol, hashish); inhalants (nitrous oxide, amyl nitrite, butyl nitrite, chlorohydrocarbons, hydrocarbons); cocaine (crack cocaine); stimulants (amphetamines, methamphetamines, Ritalin, Cylert, Preludin, Didrex, PreState, Voranil, Sandrex, Plegine); depressants (barbiturates, methaqualone, tranquilizers such as Valium, Librium, Miltown, Serax, Equanil, Tranxene); hallucinogens

(phencyclidine, lysergic acid, mescaline, peyote, psilocybin); narcotics (heroin, codeine, morphine, opium, meperidine, Percocet, Percodan, Tussionex, Fentanyl, Darvon, Talwin, Lomotil); designer drugs (analogs of fentanyl, meperidine, amphetamines, methamphetamines, and phencyclidine, for example, Ecstasy); anabolic steroids; and nicotine. The metabolic products of drugs and pharmaceutical compositions are also contemplated analytes. Analytes such as neurochemicals and other chemicals generated within the body can also be analyzed, such as, for example, ascorbic acid, uric acid, dopamine, noradrenaline, 3-methoxytyramine (3MT), 3,4-dihydroxyphenylacetic acid (DOPAC), homovanillic acid (HVA), 5-hydroxytryptamine (5HT), 5-hydroxyindoleacetic acid (FHIAA), and intermediaries in the Citric Acid Cycle.

[0134] Many embodiments described herein may use an adhesive to couple a base or housing, a sensor module, a transmitter or electronics unit, and/or a sensor to a host (e.g., to skin of the host). The adhesive can be configured for adhering to skin. The adhesive can include a pad (e.g., that is located between the adhesive and the base). Additional adhesive information, including adhesive pad information, is described in U.S. Patent Application No. 14/835,603, which was filed on August 25, 2015. The entire contents of U.S. Patent Application No. 14/835,603 are incorporated by reference herein.

[0135] As noted above, systems can apply an on-skin sensor assembly to the skin of a host. The on-skin sensor assembly may include a base that comprises an adhesive to couple a glucose sensor to the skin. Other methods are contemplated such as a strap, e.g., a watch band.

[0136] Any of the features described in the context of at least **FIG. 1** can be applicable to all aspects and embodiments identified herein. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0137] Throughout this disclosure, reference is made to an on-skin sensor assembly, which may also be described as a wearable. Such on-skin sensor assemblies (see **FIGs. 1-4** and **68-70**) may be disposable or reusable and may (see **FIGs. 68-70**) or may not (see **FIGs. 2-4**)

comprise a base or base plate. In some embodiments, on-skin sensor assemblies having a base plate (e.g., **FIGs. 68-70**) may be reusable, whereas on-skin sensor assemblies without a base plate (e.g., **FIGs. 2-4**) may be disposable. Although **FIG. 1** has already been discussed with respect to on-skin sensor assembly 160, **FIGs. 2A-4** and **68-70** describe at least some other embodiments of an on-skin sensor assembly.

[0138] **FIG. 2A** illustrates a perspective view of an on-skin sensor assembly 260, in accordance with some embodiments. On-skin sensor assembly 260 may comprise an outer housing comprising a first, top portion 292 and a second, lower portion 294. In some embodiments, the outer housing may comprise a clamshell design. On-skin sensor assembly 260 may include similar components as electronics unit 140 described above in **FIG. 1** (e.g. a potentiostat, a power source for providing power to sensor 138, signal processing components, data storage components, and a communication module (e.g., a telemetry module) for one-way or two-way data communication, a printed circuit board (PCB), an integrated circuit (IC), an Application-Specific Integrated Circuit (ASIC), a microcontroller, and/or a processor). The outer housing may feature a large rounded body having tapered end opposite the large rounded body. The outer housing may further comprise an aperture 296 disposed at the tapered end of the outer housing and adapted for sensor 238 and needle insertion. Aperture 296 may be an opening featuring a U-shaped channel extending through the tapered end of the outer housing. On-skin sensor assembly 260 may further comprise an adhesive patch 226 configured to secure on-skin sensor assembly 260 to skin of the host. As shown, adhesive patch 226 may feature an aperture 298 having a similar shape as aperture 296 and substantially aligned with aperture 296. Sensor 238 may be configured to at least partially extend through apertures 296 and 298. In some embodiments, adhesive patch 226 may comprise an adhesive suitable for skin adhesion, for example a pressure sensitive adhesive (e.g., acrylic, rubber-based, or other suitable type) bonded to a carrier substrate (e.g., spun lace polyester, polyurethane film, or other suitable type) for skin attachment, though any suitable type of adhesive is also contemplated.

[0139] On-skin sensor assembly 260 may be attached to the host with use of an applicator adapted to provide convenient and secure application. Such an applicator may also be used for inserting sensor 238 through the host's skin, and/or connecting sensor 238 to the electronics unit. Once sensor 238 has been inserted into the skin (and is connected to the electronics unit), the sensor assembly can detach from the applicator.

[0140] **FIG. 2B** illustrates a bottom perspective view of on-skin sensor assembly 260 of **FIG. 2A**. **FIG. 2B** illustrates aperture 296 disposed to a side of the outer housing, and aperture 298, each adapted for sensor 238 and needle insertion.

[0141] **FIG. 3A** illustrates a perspective view of an on-skin sensor assembly 360, in accordance with some embodiments. On-skin sensor assembly 360 may comprise an outer housing comprising a first, top portion 392 and a second, lower portion 394. In some embodiments, the outer housing may comprise a clamshell design. On-skin sensor assembly 260 may include similar components as electronics unit 140 described above in **FIG. 1** (e.g. a potentiostat, a power source for providing power to sensor 138, signal processing components, data storage components, and a communication module (e.g., a telemetry module) for one-way or two-way data communication, a printed circuit board (PCB), an integrated circuit (IC), an Application-Specific Integrated Circuit (ASIC), a microcontroller, and/or a processor). As shown, the outer housing may feature a generally oblong shape. The outer housing may further comprise an aperture 396 disposed substantially through a center portion of outer housing and adapted for sensor 338 and needle insertion through a bottom of on-skin sensor assembly 360. In some embodiments, aperture 396 may be a channel or elongated slot. On-skin sensor assembly 360 may further comprise an adhesive patch 326 configured to secure on-skin sensor assembly 360 to skin of the host. In some embodiments, adhesive patch 326 may comprise an adhesive suitable for skin adhesion, for example a pressure sensitive adhesive (e.g., acrylic, rubber-based, or other suitable type) bonded to a carrier substrate (e.g., spun lace polyester, polyurethane film, or other suitable type) for skin attachment, though any suitable type of adhesive is also contemplated. As shown, adhesive patch 396 may feature an aperture 398 aligned with aperture 396 such that sensor 338 may pass through a bottom of on-skin sensor assembly 360 and through adhesive patch 396.

[0142] **FIG. 3B** illustrates a bottom perspective view of on-skin sensor assembly 360 of **FIG. 3A**. **FIG. 3B** further illustrates aperture 396 disposed substantially in a center portion of a bottom of on-skin sensor assembly 360, and aperture 398, both adapted for sensor 338 and needle insertion.

[0143] **FIG. 4** illustrates a cross-sectional view of on-skin sensor assembly 360 of **FIGs. 3A** and **3B**. **FIG. 4** illustrates the first, top portion 392 and the second, bottom portion 394 of the outer housing, adhesive patch 326, aperture 396 in the center portion of on-skin sensor assembly

360, aperture 398 in the center portion of adhesive patch 326, and sensor 338 passing through aperture 396. The electronics unit, previously described in connection with **FIG. 3A,** may further include a circuit board 404 and a battery 402 configured to provide power to at least circuit board 404.

Applicator Embodiments

[0144] **FIG. 5** illustrates an exploded perspective view of an applicator 500 for applying on-skin sensor assembly 160 to skin 130 of a host, according to some embodiments. In some embodiments, applicator 500 may include an applicator housing 502 having an opening at its bottom and configured to house at least one or more mechanisms utilized to apply on-skin sensor assembly 160 to skin 130 of a host. Applicator housing 502 may be formed of any suitable material, e.g., a polymer, polycarbonate, ABS, nylon, polyethylene, polypropylene, etc. In some embodiments, applicator housing 502 may be configured to cover at least one feature of applicator housing 502, for example a guide of a reciprocating or back and forth mechanism, e.g., a scotch-yoke mechanism (see **FIG. 6B**).

[0145] Applicator 500 includes an activation element 504 configured to activate a drive assembly of applicator 500. In some embodiments, activation element 504 may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 500.

[0146] Applicator 500 may further comprise a needle carrier assembly 508, including an insertion element (not shown in **FIG. 5**) configured to insert sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) at least partially into skin 130 of the host. The insertion element is further illustrated in **FIG. 6H** as attaching to needle carrier assembly 508 and extending in the distal direction, substantially along an axis of insertion. In some embodiments, needle carrier assembly 508 comprises a needle carrier or shuttle. In some embodiments, the insertion element comprises a needle, for example, an open sided-needle, a deflected-tip needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. In yet other embodiments, insertion element may comprise sensor 138 itself, sufficiently rigid to be inserted partially into skin 130 of the host with minimal or no structural support, such as described in U.S. Patent No. 9,357,951, which was filed on September 29, 2010, U.S. Patent

Publication No. US 2014/0107450, which was filed on February 28, 2013, and U.S. Patent Publication No. US 2015/0289788, which was filed on April 10, 2014. The entire contents of U.S. Patent No. 9,357,951, U.S. Patent Publication No. 2014/0107450, and U.S. Patent Publication No. 2015/0289788 are incorporated by reference herein.

[0147] Applicator 500 may further comprise a drive assembly 510 configured to drive the insertion element of needle carrier assembly 508 in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position. A distal direction may be defined as extending towards an open-ended side of the applicator 500 along a path needle carrier assembly 508 is configured to travel. The distal direction may also be defined as towards the skin of a user. A proximal direction may be defined as a direction extending in a substantially opposite direction from the distal direction. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element and of needle carrier assembly 508.

[0148] Drive assembly 510 may include a rotating drive element 514 coupled to needle carrier assembly 508 via an axle 526. In some embodiments, rotating drive element 514 comprises a cam feature, e.g., a wheel cam, having a substantially circular or ovoid circumference. rotating drive element 514 may be configured to rotate with respect to needle carrier assembly 508 about an axis of rotation 518 coincident with a centerline of axle 526. rotating drive element 514 may further include a pin 516 disposed at a position on a face of rotating drive element 514 displaced radially from axis of rotation 518. Pin 516 is configured to travel in a guide (see **FIG. 6B**) of applicator housing 502.

[0149] Drive assembly 510 may further include a spring 512. Spring 512 may be a torsion spring, a clock spring, a power spring, or any other suitable type of spring. Spring 512 may be formed of any suitable material including but not limited to plastic or metal, e.g., stainless steel. In some embodiments, spring 512 is pre-compressed before activation of the applicator. In some embodiments, spring 512 is configured to be additionally loaded during activation of the applicator. Spring 512 may have a first end 520 coupled to needle carrier assembly 508 and a second end 522 coupled to rotating drive element 514. Spring 512 may be disposed coaxially with axle 526. Spring 512 may be configured to, upon activation of drive assembly 510, rotate rotating drive element 514 in a single direction with respect to needle carrier assembly 508. In some embodiments, spring 512 is configured, upon activation of drive

assembly 510, to unwind by rotating greater than zero degrees and less than 360 degrees. In some embodiments, spring 512 is pre-wound between 30 and 1440 degrees.

[0150] By virtue of rotating drive element 514 being configured to rotate with respect to needle carrier assembly 508, about axis of rotation 518, and pin 516 being restrained to travel in the guide of applicator housing 502, rotational motion of rotating drive element 514, driven by spring 512, is converted into linear, reciprocating motion of needle carrier assembly 508 along axis 590 and, therefore, of the insertion element (not shown). More specifically, rotation of rotating drive element 514 drives insertion element 508 in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position to the proximal retraction position. Such embodiments may be able to omit handoff mechanisms between aspects of drive assembly 510 that separately drive the needle carrier assembly 508 in the distal and proximate directions by virtue of a single mechanism that converts rotational motion into reciprocating linear motion.

[0151] Applicator 500 may further include a holder 524 releasably coupled to needle carrier assembly 508 and configured to guide on-skin sensor assembly 160 while coupled to needle carrier assembly 508. In some embodiments, holder 524 may also be referred to as a carrier or transport member.

[0152] **FIG. 6A-6H** illustrates cutaway and perspective views of several features of applicator 500 of **FIG. 5**, according to some embodiments. **FIG. 6A** illustrates a cutaway view of applicator 500 including applicator housing 502, activation element 504, needle carrier assembly 508, rotating drive element 514, pin 516, and holder 524. Each of these components may have functionality as previously described in connection with at least **FIG. 5**.

[0153] **FIG. 6B** illustrates guide 582 in applicator housing 502. In some embodiments, guide 582 may comprise a scotch-yoke track in which pin 516 is configured to travel upon activation of drive assembly 510, as rotating drive element 514 rotates.

[0154] **FIG. 6C** illustrates a plurality of tracks 622a, 622b, 622c in applicator housing 502 in which a respective one of a plurality of protrusions or ribs 624a, 624b, 624c of needle carrier assembly 508 are configured to slide. Accordingly, tracks 622a-622c in applicator housing 502 define a path of travel for needle carrier assembly 508. In some embodiments, this path of travel is substantially linear and longitudinal. Although three tracks and protrusions are shown in **FIG. 6C**, any number of tracks and respective protrusions are contemplated. For ease

of understanding, **FIG. 6C** illustrates a partial bottom view of applicator 500, which also shows portions of on-skin sensor assembly 160 and holder 524.

[0155] **FIG. 6D** illustrates an embodiment where needle carrier assembly 508 comprises a locking element 632 configured to prevent rotating drive element 514 from rotating. Specifically, rotating drive element 514 comprises a protrusion 634 in contact with retention element 632, which prevents protrusion 634 from traveling in a path it would otherwise take as spring 512 releases at least a portion of its stored energy in rotating drive element 514. In some embodiments, retention element 632 comprises a deflectable tab formed of a material such as a polymer, polycarbonate, ABS, nylon, polyethylene, polypropylene, or any other suitable material. Activation element 504 comprises a protrusion 640 configured to deflect retention element 632 such that protrusion 634 is no longer held by retention element 632, thereby allowing rotating drive element 514 to rotate and activating drive assembly 510. rotating drive element 514 further comprises a ridge 636 configured to limit rotation of rotating drive element 514 as rotating drive element 514 rotates and ridge 636 comes in contact with retention element 632.

[0156] **FIG. 6E** illustrates a retention element 642 of holder 524 and a stop element 644 of applicator housing 502 configured to immobilize holder 524 to applicator housing 502 upon needle carrier assembly 508 reaching the distal insertion position. In some embodiments, retention element 642 is a deflectable arm, or any other type of protrusion or snap. For example, as needle carrier assembly 508 travels in the distal direction, as a result of spring 512 turning rotating drive element 514, retention element 642 slides along an inside surface of applicator housing 502 until retention element 642 is slightly deflected by stop element 644, then snapping in an outward direction under stop element 644. At this point, needle carrier assembly 508 may be free to progress in the proximal direction as a result of spring 512 further turning rotating drive element 514. Stop element 644 will prevent retention element 642, and so holder 524, from traveling in the proximal direction. In this way, movement of needle carrier assembly 508 in the proximal direction, after reaching the distal insertion position, releases holder 524 from needle carrier assembly 508 and/or on-skin sensor assembly 160.

[0157] **FIG. 6F** illustrates a protrusion 652 of holder 524 and a protrusion 654 of applicator housing 502 configured to prevent holder 524 from travelling beyond the distal insertion position in the distal direction. For example, as holder 524 is driven in the distal

direction by needle carrier assembly 508, protrusion 652 travels along an inside surface of the applicator housing 502 until protrusion 652 comes in contact with protrusion 654, at which point holder 524 is prevented from further travel in the distal direction.

[0158] **FIG. 6G** illustrates on-skin sensor assembly 160 including a plurality of attachment points 662a-662f configured to mate with respective retention elements on needle carrier assembly 508 and/or holder 524 while traveling at least partially toward the distal insertion position, in the distal direction, during applicator activation. In some embodiments, attachment points 662a-662f are small grooves or indentations. Although a plurality of attachment points 662a-662f are illustrated, any number of attachment points are contemplated. In some embodiments, the respective retention elements may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives configured to couple on-skin sensor assembly 160 with needle carrier assembly 508 and/or holder 524.

[0159] Moreover, during pressure fluctuations, such as at high altitude or vacuum during sterilization processes for example, air present within on-skin sensor assembly 160 may exert a deforming force from within the cavity of on-skin sensor assembly 160. Although not shown in **FIG. 6G**, in some embodiments, on-skin sensor assembly 160 may have at least a portion formed with a reduced thickness or a second material (e.g. an elastomer) and, therefore, reduced strength and rigidity, such that when applicator 500 is exposed to such pressure fluctuations, the portions having the reduced thickness or second material deform in a controlled manner, thereby reducing or eliminating damage that would otherwise occur to on-skin sensor assembly 160 due to undesirable uncontrolled expansion of on-skin sensor assembly 160. The portion formed with reduced thickness or a second material may be selected to direct controlled expansion away from datum and/or retention features securing the on-skin sensor assembly to applicator assembly. Such a feature may be present in any applicator described herein.

[0160] **FIG. 6H** illustrates retention elements 672a, 672b of holder 528 configured to releasably couple on-skin sensor assembly 160 to holder 528 as needle carrier assembly 508 travels in the distal direction to the distal insertion position, and to decouple on-skin sensor assembly 160 from holder 528 as needle carrier assembly 508 travels in the proximal direction from the distal insertion position towards the proximal retraction position. Specifically, retention elements 672a, 672b may each comprise a first end 676a, 676b, a second end 678a, 678b, and a pivot point 680a, 680b. As needle carrier assembly 508 travels in the distal direction to the distal

insertion position, first end 676a, 676b of each of retention elements 672a, 672b is immobilized in a respective guide 674a, 674b of needle carrier assembly 508 and each of retention elements 672a, 672b is immobilized against interference points 682a, 682b of needle carrier assembly 508, thereby releasably coupling second ends 678a, 678b to attachment points 662a, 662b of on-skin sensor assembly 160. In some embodiments, guides 674a, 674b comprise a slot or a stop element. Since retention elements 642, 644 and/or protrusions 652, 654 immobilize holder 524 at the distal insertion position (as described in **FIG. 6E**), as needle carrier assembly 508 travels back in the proximal direction, needle carrier assembly 508 separates from holder 524, thereby separating first ends 676a, 676b of retention elements 672a, 672b from respective slots 674a, 674b, allowing first ends 676a, 676b to deflect inward and second ends 678a, 678b to deflect outward from attachment points 662a, 662b of on-skin sensor assembly 160 as retention elements 672a, 672b rotate about pivot points 680a, 680b. Although two retention elements are illustrated, any number of retention elements are contemplated. Moreover, some alternative mechanisms that may perform such retention and release actions are further described in connection with at least **FIGs. 47-50** below. Any of these alternative mechanisms are contemplated for use with applicator 500.

[0161] A brief description of the operation of applicator 500 follows with respect to **FIGs. 7A-7F**, which illustrate several perspective views of the applicator of **FIG. 5** in sequence, during operation, according to some embodiments.

[0162] **FIG. 7A** illustrates a pre-activated state of applicator 500. Applicator housing 502 and slot 582 remain stationary with respect to the skin of the host during activation. Activation element 504 is in a pre-activation position. Insertion assembly 508 is also in a pre-activation position, coupled to holder 524, which is releasably coupled to on-skin sensor assembly 160, as described in connection with at least **FIGs. 6A-6H**. At least a portion of insertion element 674 of needle carrier assembly 508 is illustrated as protruding, in a distal direction, below on-skin sensor assembly 160. Insertion element 674 may comprises a needle, for example, an open sided-needle, a needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, deflected-tip or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. Insertion element 674 may be configured to guide at least a portion of sensor 138 of on-skin sensor assembly 160. rotating drive element 514 of drive assembly 510 is shown in a pre-activation position, having pin 516 located at a first

position within guide 582 of applicator housing 502, and having protrusion 634 in contact with retention element 632. In **FIG. 7A**, pin 516 is positioned approximately 30 degrees (illustrated as clockwise, though counterclockwise is also contemplated) from a bottom dead center orientation relative to an axis of rotation of rotating drive element 514 that passes through a center of the face on which pin 516 is disposed.

[0163] **FIG. 7B** illustrates a state of applicator 500 at activation. Activation element 504 is illustrated in an activated position, having been pushed longitudinally in the distal direction by a user, for example. In the activated position, activation element 504 deflects retention element 632 such that protrusion 634 of rotating drive element 514 is unimpeded from moving, thus allowing rotating drive element 514 to rotate by the unwinding of spring 512. Since **FIG. 7B** illustrates applicator 500 just at activation, rotating drive element 514, pin 516, needle carrier assembly 508, insertion element 674, holder 524 and on-skin sensor assembly 160 are still shown in their pre-activation orientations and locations as in **FIG. 7A**. However, rotating drive element 514 will rotate in the direction of the circular arrow, and needle carrier assembly 508, insertion element 674, holder 524 and on-skin sensor assembly 160 will be driven, by pin 516 under rotating drive element 514 rotation, in the distal direction to the distal insertion position. However, the present disclosure is not so limited, and rotating drive element 514 may be configured to rotate in a direction opposite of the direction of the circular arrow.

[0164] **FIG. 7C** illustrates a state of applicator 500 during activation. Activation element 504 is illustrated in the activated position of **FIG. 7B**. rotating drive element 514 is shown as having rotated a portion of a revolution, indicated by the circular arrow, protrusion 634 having advanced beyond retention element 632. Pin 516 is shown as having moved to a second position within guide 582. This second position is shown as being to the left of the first, pre-activation position. Insertion assembly 508, insertion element 674, holder 524 and on-skin sensor assembly 160 are driven in the distal direction toward the distal insertion position when rotating drive element 514 is rotated by a force generated by spring 512.

[0165] **FIG. 7D** illustrates applicator 500 during activation, in the distal insertion position. Activation element 504 is illustrated in the activated position of **FIGs. 7B** and **7C**. rotating drive element 514 is shown as having rotated clockwise further compared to **FIG. 7C**, indicated by the circular arrow, protrusion 634 having advanced yet further beyond retention element 632. Pin 516 is shown as having moved to a third position within guide 582, shown as

being to the right of the first, pre-activation position and the second, activation position of **FIG. 7C**. Insertion assembly 508, insertion element 674, holder 524 and on-skin sensor assembly 160 are driven in the distal direction to the distal insertion position as rotating drive element 514 is further rotated by the force generated by spring 512. In this distal insertion position, at least a portion of insertion element 674 as well as at least a portion of sensor 138 of on-skin sensor assembly 160 may be inserted into skin 130 of the host. At this position, retention elements 642, 644 (see **FIG. 6**) may be engaged and protrusions 652 and 654 (see **FIG. 6**) may be in contact with one another. In **FIG. 7D**, pin 516 is positioned approximately 180 degrees (illustrated as clockwise, though counterclockwise is also contemplated) from the bottom dead center orientation relative to the axis of rotation of rotating drive element 514.

[0166] **FIG. 7E** illustrates applicator 500 during activation. Activation element 504 is illustrated in the activated position of **FIGs. 7B-7D**. rotating drive element 514 is shown as having rotated further compared to **FIG. 7D**, indicated by the circular arrow. Pin 516 is shown as having moved to a fourth position within guide 582. This fourth position is shown as being to the right of the first through third positions previously discussed. Insertion assembly 508 and insertion element 674 are now shown as being driven in the proximal direction from the distal insertion position as rotating drive element 514 is further rotated by the force generated by spring 512. Since retention elements 642, 644 (see **FIG. 6**) are engaged and protrusions 652 and 654 (see **FIG. 6**) may be in contact with one another, holder 524 and on-skin sensor assembly 160 are shown as separated from needle carrier assembly 508. In the position shown by **FIG. 7E**, on-skin sensor assembly 160 may also be decoupled from holder 524, as previously described in connection with **FIG. 6H**.

[0167] **FIG. 7F** illustrates applicator 500 post-activation. Activation element 504 is illustrated in the activated position of **FIGs. 7B-7E**. rotating drive element 514 is shown as having rotated further compared to **FIG. 7E**, indicated by the circular arrow, such that ridge 636 is in contact with retention element 632, thereby restricting further rotation of rotating drive element 514. Pin 516 is shown as having moved to a fifth position within guide 582, which is shown as being to the left of the fourth, right-most position, as pin 516 travels back along guide 582. Insertion assembly 508 and insertion element 674 are shown in the proximal retraction position. Holder 524 and on-skin sensor assembly 160 are shown as separated from needle carrier assembly 508. In the position shown by **FIG. 7F**, on-skin sensor assembly 160 may also

be decoupled from holder 524, as previously described in connection with **FIG. 6H**. In **FIG. 7F**, pin 516 is positioned approximately 330 degrees (illustrated as clockwise, though counterclockwise is also contemplated) from the bottom center orientation relative to the axis of rotation of rotating drive element 514.

[0168] **FIGs. 8-10** illustrate cutaway views of applicators 800, 900, 1000 similar to applicator 500 of **FIG. 5**, however, alternatively having activation elements 804, 904, 1004 disposed on an upper, medial, and lower side of, rather than on a top of, an applicator housing 802, 902, 1002, respectively. Applicators 800, 900, 1000 may comprise substantially all features of applicator 500 and have substantially the same operation. For example, applicator housing 802, 902, 1002, activation element 804, 904, 1004, a needle carrier assembly 808, 908, 1008, a rotating drive element 814, 914, 1014, including a pin 816, 916, 1016 and a protrusion 834, 934, 1034 and a retention element 832, 932, 1032 may correspond substantially to applicator housing 502, activation element 504, needle carrier assembly 508, rotating drive element 514 including pin 516 and protrusion 504, and retention element 502 of applicator 500, respectively.

[0169] However, in **FIG. 8**, activation element 804 is disposed on an upper side, rather than on a top, of applicator housing 802 and may be configured to, upon activation, deflect retention element 832 such that protrusion 834 no longer restrains rotating drive element 814 from rotating under force of a spring (not shown in **FIG. 8**) similar to spring 512 of applicator 500. In **FIG. 9**, activation element 904 is disposed on a medial side, rather than on a top, of applicator housing 902 and may be configured to, upon activation, deflect retention element 932 such that protrusion 934 no longer restrains rotating drive element 914 from rotating under force of a spring (not shown in **FIG. 9**) similar to spring 512 of applicator 500. As shown, due to the medial side location of activation element 904, retention element 932 may be located substantially on a side of rotating drive element 914.

[0170] In **FIG. 10**, activation element 1004 is disposed on a lower side, rather than on a top, of applicator housing 1002 and may be configured to, upon activation, deflect retention element 1032 such that protrusion 1034 no longer restrains rotating drive element 1014 from rotating under force of a spring (not shown in **FIG. 10**) similar to spring 512 of applicator 500. As shown, due to the lower side location of activation element 1004, retention element 1032 may be located substantially on a side of rotating drive element 1014. 50

[0171] An example of steps for assembling an applicator such as applicators 500, 800, 900, 1000 of **FIG. 5** and **8-10** will now be discussed in connection with **FIGs. 11A-11H.**

[0172] **FIG. 11A** illustrates coupling first end 520 of spring 512 to needle carrier assembly 508. First end 520 may be coupled to, or disposed against, a protrusion 1102 of needle carrier assembly 508 and spring 512 may be inserted around a hub 1104 of needle carrier assembly 508 such that spring 512 and hub 1104 are disposed coaxially with one another.

[0173] **FIG. 11B** illustrates coupling second end 522 of spring 512 with rotating drive element 514 and inserting axle 526 into hub 1104 of needle carrier assembly 508 within which axle 526 may rotate. Axle 526, hub 1104, and spring 512 may be disposed coaxially with respect to one another. As shown by the circular arrow, rotating drive element 514 may be rotated about axle 526 in a circular direction opposite of a direction that rotating drive element 514 rotates during activation, thereby pre-storing energy in spring 512. Axle 524 may be fully inserted into the portion of needle carrier assembly 508 such that protrusion 634 is in contact with retention element 632, thereby preventing rotating drive element 514 from rotating until activation. In some embodiments, rotating drive element 514 may be rotated about axle 504 such that spring 512 is only partially wound. In such embodiments, spring 512 may be fully wound at a later stage of assembly. Although **FIG. 11B** illustrates rotating drive element 514 as having a male-type aspect configured to mate with a female-type aspect of hub 1104, the present disclosure also contemplates rotating drive element 514 as having a female-type aspect configured to mate with a male-type aspect of hub 1104.

[0174] **FIG. 11C** illustrates pushing retention elements 672a, 672b toward a center of holder 524 and coupling holder 524 to needle carrier assembly 508 by seating first ends 676a, 676b of retention elements 672a, 672b into respective slots 674a, 674b of needle carrier assembly 508.

[0175] **FIG. 11D** illustrates coupling on-skin sensor assembly 160 to holder 524 by snapping second ends 678a, 678b (not shown in **FIG. 11D**) of retention elements 672a, 672b into attachment points 662a, 662b of on-skin sensor assembly 160. In some embodiments, retention elements 672a, 672b may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives.

[0176] **FIG. 11E** illustrates inserting the assembled needle carrier assembly 508, rotating drive element 514, holder 524, and on-skin sensor assembly 160 into applicator housing 502

through the opening in the bottom of applicator housing 502 and through a vertical portion of guide 582 (see **FIG. 11F**). During such insertion, pin 516 of rotating drive element 514 is inserted along at least the vertical portion of guide 582 in applicator housing 502, as shown in **FIG. 11F**. Accordingly, spring 512 (not shown in **FIGs. 11E, 11F**) may not be fully wound at this point, instead being partially wound to the extent that pin 516 of rotating drive element 514 is positioned to be inserted along guide 582 in applicator housing 502.

[0177] **FIG. 11G** illustrates positioning the assembled needle carrier assembly 508, rotating drive element 514, holder 524, and on-skin sensor assembly 160 further in the proximal direction into applicator housing 502 such that pin 516 of rotating drive element 514 follows guide 582 of applicator housing 502, thereby turning rotating drive element 514 fully winding spring 512 (not shown in **FIG. 11G**) and positioning protrusion 634 in contact with retention element 632 such that the drive assembly, comprising at least rotating drive element 514, having pin 516, and spring 512, are loaded for activation.

[0178] **FIG. 11H** illustrates a magnified cutaway view of area 1106 of **FIG. 11G** illustrating the relationship between rotating drive element 514, pin 516, guide 582, protrusion 634 and retention element 632.

[0179] **FIG. 11J** illustrates inserting activation element 504 into applicator housing 502.

[0180] **FIG. 12** illustrates an exploded perspective view of another applicator 1200 for applying an on-skin sensor assembly to a skin of a host, according to some embodiments. Applicator 1200 may include an applicator housing 1202 having an opening in its bottom and configured to house at least one or more mechanisms utilized to apply on-skin sensor assembly 160 to skin 130 (see **FIG. 2**) of a host.

[0181] Applicator 1200 includes an activation element 1204 configured to activate a drive assembly of applicator 1200. In some embodiments, activation element 1204 may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 1200.Applicator 1200 may further comprise a needle carrier assembly 1208, including an insertion element (not shown in **FIG. 12**) configured to insert sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) into skin 130 of the host. In some embodiments, the insertion element comprises a needle, for example a C-needle, as will be described in more detail in connection with at least **FIGs. 47-50**.

[0182] Applicator 1200 may further comprise a drive assembly 1210 configured to drive the insertion element of needle carrier assembly 1208 in the distal direction to a distal insertion position and in the proximal direction from the distal insertion position to a proximal retraction position. A distal direction may be defined as extending towards an open-ended side of the applicator 1200 along a path needle carrier assembly 1208 is configured to travel. The distal direction may also be defined as towards the skin of a user. A proximal direction may be defined as a direction extending in a substantially opposite direction from the distal direction. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element and of needle carrier assembly 1208.

[0183] Drive assembly 1210 may include a spring 1212 having a first tang 1220 (e.g., end) and a second tang 1222 (e.g., end). Spring 1212 may be a torsion spring, a double torsion spring, or any other suitable type of spring. Spring 1212 may be supported by a spring spool 1250 comprising a first portion 1250a and an optional second portion 1250b. In some embodiments, spring 1212 is self-supporting and is not supported by a spring spool. First portion 1250a may be configured to couple with second portion 1250b such that spring spool 1250 is disposed coaxially with spring 1212 and provides support for spring 1212 along an axis of rotation 1218 of spring 1212. As will be shown in more detail in connection with **FIG. 13**, first tang 1220 of spring 1212 may be coupled to applicator housing 1202, e.g., to a hook or protrusion of applicator housing 1202. Second tang 1222 may be coupled to needle carrier assembly 1208, e.g., a hook or protrusion of needle carrier assembly 1208. Upon activation of drive assembly 1210, first tang 1220 and second tang 1222 of spring 1212 unwind in opposite clockwise or counterclockwise directions, thereby driving spring 1212 in an arc and insertion element 1208 in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position. The arc through which drive assembly 1210 travels may extend in a direction approximately perpendicular to the distal direction and the proximal direction, or in an arc defined by the tangs of the spring and the rotation points.

[0184] Applicator 1200 may further include a holder 1224 releasably coupled to needle carrier assembly 1208 and configured to guide on-skin sensor assembly 160 while coupled to needle carrier assembly 1208. In some embodiments, holder 1224 may comprise a stripper plate. As will be described in more detail below, on-skin sensor assembly 160 may be stripped from

holder 1224 and needle carrier assembly 1208 once on-skin sensor assembly 160 is disposed on skin 130 of the host.

[0185] **FIG. 13A-13F** illustrate perspective and cutaway views of several features of applicator 1200 of **FIG. 12**, according to some embodiments. **FIG. 13A** illustrates a cross-sectional view of applicator 1200, including applicator housing 1202 having retention element 1334, activation element 1204, spring spool 1250, spring 1212 having first tang 1220 and second tang 1222, needle carrier assembly 1208 having retention element 1332, holder 1224, and on-skin sensor assembly 160. In some embodiments, retention element 1332 may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives configured to couple on-skin sensor assembly 160 with needle carrier assembly 1208 and/or holder 1224. Each of these components may have functionality as previously described in connection with at least **FIG. 12**. Moreover, first tang 1220 is configured to, upon activation of the drive assembly, rotate about a rotation point 1336. Second tang 1222 is similarly configured.

[0186] **FIG. 13F** illustrates a magnified perspective view of a retention element 1342 of holder 1224 and a stop element 1344 of applicator housing 1202 configured to immobilize holder 1228 to applicator housing 1202 upon needle carrier assembly 1208 reaching the distal insertion position. In some embodiments, retention element 1342 is a deflectable arm. For example, as needle carrier assembly 1208 travels in the distal direction, as a result of spring 1212 partially unwinding, retention element 1342 slides along an inside surface of applicator housing 1202 and is deflected by stop element 1344 until retention element 1342 snaps under stop element 1344. In some embodiments, the functionality between retention element 1342 and stop element 1344 may be swapped, e.g., stop element 1344 may be configured to be deflected by and snap over retention element 1342. At this point, though needle carrier assembly 1208 may be free to progress in the proximal direction, as a result of spring 1212 unwinding further, stop element 1344 will prevent retention element 1342, and so holder 1224, from traveling back in the proximal direction. In this way, movement of needle carrier assembly 1208 in the proximal direction after reaching the distal insertion position allows holder 1224 and/or needle carrier assembly 1208 to be released from on-skin sensor assembly 160.

[0187] **FIG. 13B** illustrates a magnified cutaway view of a portion of needle carrier assembly 1208 comprising a retention element 1332 configured to interlock with a retention element 1334 of applicator housing 1202 and prevent needle carrier assembly 1208 from

separating from applicator housing 1202 in the loaded, pre-activated position. Activation element 1204 is configured to deflect retention element 1332 such that retention element 1334 no longer holds retention element 1332, thereby allowing spring 1212 to separate needle carrier assembly 1208 from applicator housing 1202 and activating drive assembly 1210.

[0188] **FIG. 13C** illustrates a magnified view of second tang 1222 of a spring coupled to needle carrier assembly 1208, for example, via a hook 1348 configured to immobilize second tang 1222 to needle carrier assembly 1208. The fastening concept described for second tang 1222 in **FIG. 13C** may also be utilized for first tang 1220.

[0189] **FIG. 13D** illustrates on-skin sensor assembly 160 including a plurality of attachment points 662a-662c configured to mate with respective retention elements 1372a-1372c on needle carrier assembly 1208 and/or holder 1224 while traveling in the distal direction at least partially toward the distal insertion position during applicator activation. In some embodiments, where holder 1224 comprises a stripper plate, holder 1224 may function similarly to a stripper plate in punch and die manufacturing or injection molding processes. Although a plurality of attachment points 662a-662c are illustrated, any number of attachment points are contemplated. In some embodiments, retention elements 1372a-1372c may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives.

[0190] Retention elements 1372a-1372c of needle carrier assembly 1208 and/or holder 1224 are configured to releasably couple on-skin sensor assembly 160 to holder 1228 as needle carrier assembly 1208 travels in the distal direction to the distal insertion position, and to decouple on-skin sensor assembly 160 from needle carrier assembly 1208 and/or holder 1228 as needle carrier assembly 1208 travels in the proximal direction from the distal insertion position towards the proximal retraction position. Specifically, since retention elements 1342, 1344 immobilize holder 1224 from traveling in the proximal direction at the distal insertion position, as needle carrier assembly 1208 travels back in the proximal direction. This causes needle carrier assembly 1208 to separate from holder 1224 and on-skin sensor assembly 160, thereby decoupling retention elements 1372a-1372c from attachment points 662a-662c of on-skin sensor assembly 160. Although two retention elements are illustrated, any number of retention elements are contemplated. Moreover, alternative mechanisms that may perform such retention and release actions are further described in connection with at least **FIGs. 47-50** below. Any of these alternative mechanisms are contemplated for use with applicator 1200.

[0191] **FIG. 13E** illustrates a perspective view of a plurality of tracks 1322a, 1322b, 1322c in applicator housing 1202 in which a respective plurality of protrusions 1324a, 1324b, 1324c of needle carrier assembly 1208 are configured to slide. Accordingly, tracks 1322a-1322c in applicator housing 1202 define a path of travel for needle carrier assembly 1208. In some embodiments, this path of travel is substantially linear and longitudinal. Although three tracks and protrusions are shown in **FIG. 13E**, a single track or a plurality of tracks and respective protrusions are contemplated.

[0192] A brief description of the operation of applicator 1200 follows with respect to **FIGs. 14A-14E**, which illustrate several cross-sectional views of the applicator of **FIG. 12** during operation, according to some embodiments.

[0193] **FIG. 14A** illustrates a state of applicator 1200 at activation. Activation element 1204 is illustrated in an activated position, having been pushed longitudinally in the distal direction by a user, for example. In the activated position, activation element 1204 deflects retention element 1332 such that retention element 1334 of applicator housing 1202 does not prevent needle carrier assembly 1208 from moving when spring 1212 unwinds from a pre-wound state. Since **FIG. 14A** illustrates applicator 1200 just at activation, spring 1212, needle carrier assembly 1208, holder 1224 and on-skin sensor assembly 160 are shown in their pre-activation orientations and locations. However, spring 1212 will unwind partially and needle carrier assembly 1208, holder 1224 and on-skin sensor assembly 160 will be driven, by such unwinding, in the distal direction to the distal insertion position.

[0194] **FIG. 14B** illustrates a state of applicator 1200 during activation. Activation element 1204 is illustrated in the activated position of **FIG. 14A**. Spring 1212 has partially unwound such that first tang 1220 unwinds in a first arc-direction and second tang 1222 unwinds in a second arc-direction opposite of the first arc-direction. Spring 1212 travels through an arc-direction approximately perpendicular to the distal direction and the proximal direction, or in an arc defined by the tangs of spring 1212 and their associated rotation points. As a result, needle carrier assembly 1208, insertion element 1374, holder 1224 and on-skin sensor assembly 160 are driven in the distal direction toward the distal insertion position by a force generated by spring 1212.

[0195] **FIG. 14C** illustrates applicator 1200 during activation, in a distal insertion position. Activation element 1204 is illustrated in the activated position of **FIGs. 14A** and **14B**.

Spring 1212 has unwound further, relative to its position as illustrated in **FIGs. 14A** and **14B**, substantially in the direction of the horizontal arrow. Insertion assembly 1208, holder 1224 and on-skin sensor assembly 160 are driven in the distal direction to the distal insertion position by the force generated by spring 1212. In this distal insertion position, at least a portion of an insertion element coupled to needle carrier assembly 1208 similarly to that shown in **FIG. 6** (not shown in **FIGs. 14A-14E**) as well as at least a portion of sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) may be inserted into skin 130 of the host. At this position, although not shown, retention elements 1342, 1344 (see **FIG. 13**) may be engaged with one another.

[0196] **FIG. 14D** illustrates applicator 1200 during activation. Activation element 1204 is illustrated in the activated position of **FIGs. 14A-14C**. Spring 1212 has further unwound and travelled in substantially the same direction as shown by the arrow. Where unwinding of spring 1212 in **FIGs. 14A-14C** caused movement of the needle carrier assembly 1208 in the distal direction, because spring 1212 is now on an opposite side of the points at which the first tang 1220 and the second tang 1222 are anchored, further unwinding of spring 1212 results in movement of the needle carrier assembly 1208 in the proximal direction toward the proximal retraction position. Since the retention elements (see **FIG. 13**) are engaged, holder 1224 and on-skin sensor assembly 160 are shown as separated from needle carrier assembly 1208. In the position shown by **FIG. 14D**, on-skin sensor assembly 160 may also be decoupled from holder 1224, as previously described in connection with call-out 1330 of **FIG. 13**.

[0197] **FIG. 14E** illustrates applicator 1200 post-activation. Activation element 1204 is illustrated in the activated position of **FIGs. 14A-14D**. Spring 1212 is illustrated as having unwound further compared to its position as illustrated in **FIG. 14D** and having travelled substantially in the direction indicated by the arrow. Insertion assembly 1208 has travelled in the proximal direction indicated by the vertical arrow to the proximal retraction position. Holder 1224 and on-skin sensor assembly 160 are shown as separated from needle carrier assembly 1208.

[0198] **FIGs. 15-17** illustrate perspective views of several exemplary double torsional springs that support different configurations of applicator 1200, according to some embodiments. Accordingly, any of the springs described by **FIGs. 15-17** may be utilized for spring 1212 previously discussed in connection with **FIGs. 12-14E**. As shown in **FIGs. 15-17**, different

shaped and/or sized cross-bridges 1522c, 1622c, 1722c of springs 1512, 1612, 1712 may be provided by flaring one or more tangs in a particular direction.

[0199] For example, **FIGs. 15-17** illustrate double torsional springs 1512, 1612, 1712, each comprising a first winding 1512a, 1612a, 1712a and a second winding 1512b, 1612b, 1712b. Double torsional springs 1512, 1612, 1712 may be formed from a single segment of suitable material, e.g., metal or plastic. First windings 1512a, 1612a, 1712a each comprise a first tang 1520a, 1620a, 1720a and a second tang 1522a, 1622a, 1722a. Second windings 1512b, 1612b, 1712b each comprise a first tang 1520b, 1620b, 1720b and a second tang 1522b, 1622b, 1722b. For each spring 1512, 1612, 1712, second tangs 1522a, 1522b; 1622a, 1622b; 1722a, 1722b may be coupled to one another by a cross-bridge 1522c, 1622c, 1722c. Cross-bridge 1522c of **FIG. 15** may have a length substantially equal to a spacing 1530 between first winding 1512a and second winding 1512b defined by the extension of second tangs 1522a, 1522b from first winding 1512a and second winding 1512b, respectively. Cross-bridge 1622c of **FIG. 16** may have a length exceeding a spacing 1630 between first winding 1612a and second winding 1612b defined by the extension of second tangs 1622a, 1622b from first winding 1612a and second winding 1612b, respectively, due to second tang 1622b of second winding 1612b being flared toward first tang 1620b of second winding 1612b. Cross-bridge 1722c of **FIG. 17** may have a length exceeding a spacing 1730 between first winding 1712a and second winding 1712b defined by the extension of second tangs 1722a, 1722b from first winding 1712a and second winding 1712b, respectively, due to second tang 1722a of first winding 1712a being flared toward first tang 1720a of first winding 1712a and second tang 1722b of second winding 1712b being flared toward first tang 1720b of second winding 1712b to provide the increased length of cross-bridge 1722c compared to either cross-bridge 1522c shown in **FIG. 15** or cross-bridge 1622c shown in of **FIG. 16**.

[0200] **FIGs. 18-23** illustrate alternative drive assemblies for utilization in applicators, such as applicator 1200 of **FIG. 12**, according to some embodiments. **FIG. 18** illustrates a drive assembly comprising a linkage element 1850. In some embodiments, linkage element 1850 may comprise a flex linkage. The flex linkage may contain one or more living hinge(s). In other embodiments, linkage element 1850 may comprise at least two discrete sections configured to pivot about a hinge coupling the at least two discrete sections.

[0201] A flex linkage is a type of hinge assembly formed from an extension of a parent material (e.g., polypropylene plastic). The hinge flex linkage is a thin section of the parent material that acts as a bending connection with two larger sections of the parent material. Typically, the larger sections of the parent material as well as the hinge will be made of one continuous piece of the parent material. Since it is relatively thin and typically made from flexible materials, the flex linkage is also able to rotate about one axis by 180 degrees or more – potentially for many thousands or even millions of cycles. Contrary to most hinges, which involve multiple parts assembled in a traditional pivoting mechanism, flex linkages are not a separate entity. They may be described as a purposeful fault line at a predetermined point in the material which is designed such that it does not fail after repeated bending.

[0202] Linkage element 1850 has a first end 1852 coupled to an applicator housing 1802, a second end 1854 coupled to a needle carrier assembly 1808, and a hinge 1856 disposed between first end 1852 and second end 1854.

[0203] The drive assembly further comprises a spring 1812, which in some embodiments may be a single or double torsion spring. Spring 1812 comprises a first tang 1820 coupled to applicator housing 1802 and/or to linkage element 1850 at first end 1852 or at a position between first end 1852 and hinge 1856. Spring 1812 further comprises a second tang 1822 coupled to needle carrier assembly 1808 and/or to linkage element 1850 at second end 1854 or at a position between second end 1854 and hinge 1856. In some embodiments, hinge 1856 may be aligned with an axis of rotation 1818 of spring 1812 to provide smooth operation as well as to reduce any stresses caused by incompatible movement between linkage element 1850 and spring 1812.

[0204] Applicator 1200, utilizing drive assembly 1810, may function substantially as described for applicator 1200 of **FIG. 12**, however, further including that first end 1852, second end 1854 and hinge 1856 of linkage element 150 move substantially in alignment with first tang 1820, second tang 1822 and axis of rotation 1818 of spring 1812, respectively, during activation.

[0205] **FIG. 19** illustrates another drive assembly comprising a linkage element 1950. Linkage element 1950 has a first end 1952 coupled to an applicator housing 1902, a second end 1954 coupled to a needle carrier assembly 1908, and a hinge 1956 disposed between first end 1952 and second end 1954. The drive assembly further comprises a spring 1912, which in some embodiments may be a single or double torsion spring. Spring 1912 comprises a first tang 1920 coupled to linkage element 1950 between second end 1954 and hinge 1956. Spring 1912 further

comprises a second tang 1922 coupled to needle carrier assembly 1908. Upon activation, spring 1912 unwinds and first tang 1952 sweeps an arc while second tang 1954 is held substantially stationary against needle carrier assembly 1908. As first tang 1952 sweeps its arc, first tang 1952 drives linkage element 1950 from the bent position shown, hinge 1956 pivoting, until linkage element 1950 is substantially vertical, and then continuing pivoting until linkage element 1950 is in a substantially mirror orientation from that shown in **FIG. 19**. This motion drives needle carrier assembly 1908 in the distal direction, reaching the distal insertion position when linkage element 1950 is substantially vertical, and then increasingly in the proximal direction as linkage element 1950 is further driven from the substantially vertical orientation to the substantially mirrored orientation to that shown in **FIG. 19**.

[0206] **FIG. 20** illustrates another drive assembly comprising a linkage element 2050. Linkage element 2050 has a first end 2052 coupled to an applicator housing 2002, a second end 2054 coupled to a needle carrier assembly 2008, and a hinge 2056 disposed between first end 2052 and second end 2054. The drive assembly further comprises a spring 2012, which in some embodiments may be a single or double torsion spring. Spring 2012 comprises a first tang 2020 coupled to linkage element 2050 between first end 2052 and hinge 2056. Spring 2012 further comprises a second tang 2022 coupled to applicator body 2002. Upon activation, spring 2012 unwinds and first tang 2052 sweeps an arc while second tang 2054 is held substantially stationary against applicator body 2002. As first tang 2052 sweeps its arc, first tang 2052 drives linkage element 2050 from the bent position shown, hinge 2056 pivoting, until linkage element 2050 is substantially vertical, and then continuing pivoting until linkage element 2050 is in a substantially mirror orientation from that shown in **FIG. 20**. This motion drives needle carrier assembly 2008 in the distal direction, reaching the distal insertion position when linkage element 2050 is substantially vertical, and then increasingly in the proximal direction as linkage element 2050 is further driven from the substantially vertical orientation to the substantially mirrored orientation to that shown in **FIG. 20**.

[0207] **FIG. 21** illustrates another drive assembly comprising a linkage element 2150. Linkage element 2150 has a first end 2152 coupled to an applicator housing 2102, a second end 2154 coupled to a needle carrier assembly 2108, and a hinge 2156 disposed between first end 2152 and second end 2154. The drive assembly further comprises a spring 2112, which in some embodiments may be an extension spring. A compression spring is also contemplated. However,

a compression spring may be coupled between hinge 2156 and the closer side of applicator housing 2102. Spring 2112 comprises a first end 2120 coupled to linkage element 2150 and a second end 2122 coupled to applicator body 2102. In some embodiments, first end 2120 is coupled to linkage element 2150 between first end 2152 and hinge 2156. In other embodiments first end 2120 is coupled to linkage element 2150 at hinge 2156. In yet other embodiments first end 2120 is coupled to linkage element 2150 between hinge 2156 and second end 2154. Upon activation, spring 2112 unwinds through an arc that extends in a direction approximately perpendicular to the distal direction and the proximal direction, or in an arc defined by the tangs of the spring and their respective rotation points, driving linkage element 2150 from the bent position shown, hinge 2156 pivoting, until linkage element 2150 is substantially vertical, and then continuing pivoting until linkage element 2150 is in a substantially mirror orientation from that shown in **FIG. 21**. This motion drives needle carrier assembly 2108 in the distal direction, reaching the distal insertion position when linkage element 2150 is substantially vertical, and then increasingly in the proximal direction as linkage element 2150 is further driven from the substantially vertical orientation to the substantially mirrored orientation to that shown in **FIG. 21**.

[0208] **FIG. 22** illustrates another drive assembly comprising a leaf spring 2212. Leaf spring 2212 comprises a first end 2220 coupled to an applicator housing 2202 and a second end 2222 coupled to a needle carrier assembly 2208. Upon activation, leaf spring 2212 unloads in a direction substantially parallel to the axis of insertion, driving needle carrier assembly 2208 to the distal insertion position when leaf spring 2212 is unloaded.

[0209] **FIG. 23** illustrates another drive assembly comprising a linkage element 2350. Drive assembly 2310 is substantially the same as drive assembly 1910 except replacing torsion spring 1912 with leaf spring 2312. Linkage element 2350 has a first end 2352 coupled to an applicator housing 2302, a second end 2354 coupled to a needle carrier assembly 2308, and a hinge 2356 disposed between first end 2352 and second end 2354. The rive assembly further comprises leaf spring 2312 having a first end 2320 coupled to linkage element 2350 between second end 2354 and hinge 2356, and a second end 2322 coupled to needle carrier assembly 2308. Upon activation, spring 2312 unloads and first end 2320 sweeps an arc while second end 2322 is held substantially stationary against needle carrier assembly 2308. As first end 2320 sweeps its arc, first end 2320 drives linkage element 2350 from the bent position shown, hinge

2356 pivoting, until linkage element 2350 is substantially vertical, and then continuing pivoting until linkage element 2350 is in a substantially mirror orientation from that shown in **FIG. 23**. This motion drives needle carrier assembly 2308 in the distal direction, reaching the distal insertion position when linkage element 2350 is substantially vertical, and then increasingly in the proximal direction as linkage element 2350 is further driven from the substantially vertical orientation to the substantially mirrored orientation to that shown in **FIG. 23**.

[0210] An example of steps for assembling an applicator such as applicator 1200 of **FIG. 12** will now be discussed in connection with **FIGs. 24A-24M**. To the extent any step is compatible, the assembly steps of **FIGs. 24A-24M** may also apply to any applicator utilizing the drive assemblies described in connection with **FIGs. 18-23**.

[0211] **FIG. 24A** illustrates coupling first portion 1250a and second portion 1250b of spring spool 1250 together inside the windings of spring 1212. **FIG. 24B** illustrates the assembled spring spool 1250 and spring 1212. Spring spool 1250 and spring 1212 are disposed coaxially with one another. **FIG. 24C** illustrates spring 1212 before winding in the direction indicated by the circular arrow, having first tang 1220 and second tang 1222 in the illustrated positions. **FIG. 24D** illustrates spring 1212 after winding, having first tang 1220 and second tang 1222 in the illustrated positions.

[0212] **FIG. 24E** illustrates coupling wound spring 1212 to needle carrier assembly 1208. In some embodiments, this includes coupling first tang 1220 to a hook 1348 of needle carrier assembly 1208 and coupling second tang 1222 to or disposing second tang 1222 against needle carrier assembly 1208. **FIG. 24F** illustrates a side view of wound spring 1212 coupled to needle carrier assembly 1208, while **FIG. 24G** illustrates a perspective view of the arrangement shown in **FIG. 24F**.

[0213] **FIG. 24H** illustrates coupling holder 1224 to needle carrier assembly 1208 and on-skin sensor assembly 160 to holder 1224. **FIG. 24J** illustrates a side view of on-skin sensor assembly 160, holder 1224, and needle carrier assembly 1208 assembled, while **FIG. 24K** illustrates a perspective view of the arrangement shown in **FIG. 24J**.

[0214] **FIG. 24L** illustrates assembling the complex including on-skin sensor assembly 160, holder 1224, needle carrier assembly 1208, and spring 1212 into applicator housing 1202 through the opening in the bottom of applicator housing 1202, and insertion of activation

element 1204 into applicator housing 1202. **FIG. 24M** illustrates the result of the assembly shown in **FIG. 24L**.

[0215] **FIG. 25** illustrates an exploded perspective view of yet another applicator 2500 for on-skin sensor assembly 160 of an analyte sensor system, according to some embodiments. Applicator 2500 may include an applicator housing 2502 configured to house one or more mechanisms for applying on-skin sensor assembly 160 to skin 130 of a host. Applicator housing 2502 may be formed of any suitable material, e.g., a polymer, polycarbonate, ABS, nylon, polyethylene, polypropylene, etc.

[0216] Applicator 2500 includes an activation element 2504 configured to activate a drive assembly of applicator 2500. In some embodiments, activation element 2504 may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 2500.Applicator 2500 may further comprise a needle carrier assembly 2508, including an insertion element 2574 configured to insert sensor 138 (e.g., **FIG. 1**) of on-skin sensor assembly 160 (e.g., **FIG. 1**) into skin 130 (e.g., **FIG. 1**) of the host. In some embodiments, insertion element 2574 comprises a needle, for example, an open sided-needle, a needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. In yet other embodiments, insertion element may comprise sensor 138, sufficiently rigid to be inserted partially into skin 130 of the host with minimal or no structural support.

[0217] Applicator 2500 may further comprise a drive assembly 2510 configured to drive insertion element 2574 of needle carrier assembly 2508 in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position.

[0218] Applicator 2500 may further include a holder 2524 releasably coupled to needle carrier assembly 2508 and configured to guide on-skin sensor assembly 160 while coupled to needle carrier assembly 2508. As will be described in more detail below, on-skin sensor assembly 160 may be stripped from holder 2524 and needle carrier assembly 2508 once on-skin sensor assembly 160 is disposed on skin 130 of the host.

[0219] Drive assembly 2510 may include a spring 2512, which may be any suitable type of spring, e.g., a compression spring, extension spring, leaf spring, flex arm spring, etc. Spring

2512 may have a first end 2520 coupled to applicator housing 2502 and a second end coupled to needle carrier assembly 2508. Spring 2520 may be configured to, upon activation of drive assembly 2510, drive needle carrier assembly 2508 in the distal direction. In some embodiments, spring 2512 may be pre-loaded, e.g., at the factory. In some other embodiments, spring 2512 may be loaded by an action of the user of applicator 2500.

[0220] Drive assembly 2510 further includes a spring 2528 that may be coupled to an applicator base 2530 of applicator 2500. In some embodiments, spring 2528 may be a compression spring, extension spring, leaf spring, flex arm spring, etc. In some embodiments, spring 2528 may be pre-loaded, e.g., at the factory. In some other embodiments, spring 2528 may be loaded by an action of the user. In yet other embodiments, spring 2528 may be loaded by unloading of spring 2512. Spring 2528 may comprise one or more portions configured to drive needle carrier assembly 2508 in the proximal direction from the distal insertion position, as will be described in more detail below.

[0221] **FIG. 26A-26D** illustrate several cutaway views and a bottom view of several features of applicator 2500 of **FIG. 25**, according to some embodiments. **FIG. 26A** illustrates a perspective cutaway view of applicator 2500 including applicator housing 2502, activation element 2504, applicator base 2530 including protrusion 2602, spring 2512, leaf spring(s) 2528, needle carrier assembly 2508, holder 2524, and on-skin sensor assembly 160. Each of these components may have functionality as previously described in connection with at least **FIG. 25**.

[0222] **FIG. 26B** illustrates a perspective view of several features of holder 2524, applicator base 2530 and activation element 2504. Spring 2512 is configured to be coupled to applicator housing 2502 at a first end and to holder 2524 at a second end. In a pre-activation state, spring 2512 may be configured to store energy for driving holder 2512 (and needle carrier assembly 2508) in the distal direction to the distal insertion position upon activation. Holder 2524 comprises an axle 2614 configured to snap into applicator base 2530 such that holder 2524 is configured to pivot in a substantially circular arc about axle 2614. In **FIG. 26B**, activation element 2504 is illustrated as comprising a protrusion 2612 configured to guide holder 2524 in the pre-activation position shown until activation element 2504 is activated, thereby displacing protrusion 2612 from its pre-activation orientation relative to holder 2524 and releasing holder 2524. **FIG. 26B** further illustrates that leaf spring(s) 2528 are not coupled to holder 2524. Instead, leaf spring(s) 2528 are coupled to needle carrier assembly 2508 and are configured to

drive needle carrier assembly 2508 in the proximal direction from the distal insertion position. Although activation element 2504 is shown as a button, the present disclosure further contemplates activation element 2504 as a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 2500. Moreover, although activation element 2504 is illustrated as being disposed on a side of applicator housing 2502, the present disclosure contemplates any other location, e.g., on a top, bottom, or other side location of applicator housing 2502, and/or any other angle of disposition with respect to applicator housing 2502.

[0223] **FIG. 26C** illustrates an exploded perspective view of needle carrier assembly 2508, insertion element 2674, and holder 2524. Insertion element 2674 is coupled to needle carrier assembly 2508. In some embodiments, insertion element 2674 comprises an open-sided needle configured to guide and insert sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) into skin 130 of the host. Insertion assembly 2508 is coupled at a first end to axle 2614 of holder 2524. Insertion assembly 2508 further comprises a retention element 2622 configured to releasably couple a second end of needle carrier assembly 2508 to holder 2524. Insertion assembly 2508 further comprises a retention element 2604 configured to releasably couple on-skin sensor assembly 160 to needle carrier assembly 2508 and holder 2524. In some embodiments, retention element 2604 may comprise a snap fit, friction fit, interference feature, elastomeric grip and/or adhesive configured to couple on-skin sensor assembly 160 with needle carrier assembly 2508 and/or holder 2524. Spring 2512 is configured to, upon activation of applicator 2500, drive needle carrier assembly 2508 and holder 2524 in the distal direction along a circular arc defined by axle 2614 to the distal insertion position. Spring 2512 transfers at least a portion of its stored energy to leaf spring(s) 2528 as needle carrier assembly 2508 is driven in the distal direction along the circular arc. In some other embodiments, leaf spring(s) 2528 may be pre-loaded such that spring 2512 does not transfer stored energy leaf spring(s) 2528. As needle carrier assembly 2508 is driven in the distal direction, a protrusion 2602 of applicator base 2530 is configured to deflect retention element 2622 sufficiently to separate needle carrier assembly 2508 from holder 2524 substantially at the distal insertion position, thereby uncoupling the second end of needle carrier assembly 2508 from holder 2524. Accordingly, from the distal insertion position, leaf spring(s) 2528, now loaded, are configured to drive needle carrier

assembly 2508 in the proximal direction from the distal insertion position, along the circular arc, to the proximal retraction position.

[0224] **FIG. 26D** illustrates a portion 2632 of activation element 2504 coupled to applicator housing 2502 and configured to act as a return spring, returning activation element 2504 to its pre-activation position after activation. For example, as activation element 2504 is pressed to the right as shown in **FIG. 26D**, portion 2632 is deformed against applicator housing 2502, thereby functioning substantially as a spring, which when unloaded, returns activation element 2504 to its pre-activation position.

[0225] **FIGs. 27A-27E** illustrate several cross-sectional views of applicator 2500 of **FIG. 25** during operation, according to some embodiments. **FIG. 27A** illustrates applicator 2500 at the time of activation. For example, activation element 2504 is illustrated in an activated position, e.g., pushed inwardly, which releases holder 2524 from its immobilized, pre-activation state. Spring 2512, needle carrier assembly 2508, insertion element 2674, holder 2524, and on-skin sensor assembly 160 are all shown in their pre-activation positions.

[0226] **FIG. 27B** illustrates applicator 2500 during activation. Spring 2512 is driving holder 2524, and so releasably coupled needle carrier assembly 2508, insertion element 2674, and on-skin sensor assembly 160, in the distal direction along the circular arc defined by axle 2614. In some embodiments, a radius of the circular arc may be between 20 millimeters (mm) and 80mm, inclusive, although radiuses larger or smaller than this range are also contemplated.

[0227] The radius of this circular arc may depend on one or more of a distance from the skin of the host to axle 2614, a height of the on-skin sensor assembly 160 from a bottom opening or surface of applicator 2500 or from axle 2614, and/or a location of sensor 138 within on-skin sensor assembly 160. Selection of a radius may be made at least in part to minimize tissue trauma, optimize deployment of sensor 138, and to minimize insertion and/or retraction friction between the insertion member and the tissue of the host.

[0228] For example, an angle 2710 (see **FIG. 27A**) between a needle axis and a bottom plane of on-skin sensor assembly may be calculated such that a minimum offset is achieved between the straight needle path and the ideal curved profile. In some embodiments, it has been determined that an approximately 71 degree angle between the needle axis and the bottom plane of on-skin sensor assembly produces less lateral motion of the tip of the insertion element within the skin of the host compared to an approximately 90 degree angle between the needle axis and

the bottom plane of on-skin sensor assembly. However, this angle may depend on at least some of the same factors affecting an ideal radius of the circular arc.

[0229] Moreover, various needle geometries may be utilized, including, but not limited to, straight needle geometries, kinked needle geometries (e.g., two or more substantially straight portions with one or more bends disposed therebetween), and fully or partially curved needle geometries (e.g., a curved distal portion configured to at least partially pierce the skin of the host with or without a straight proximal portion), as described in more detail in connection with at least **FIGs. 47-50**.

[0230] **FIG. 27C** illustrates applicator 2500 in the distal insertion position. Spring 2512 has driven holder 2524, and so releasably coupled needle carrier assembly 2508, insertion element 2674, and on-skin sensor assembly 160, in the distal direction to the distal insertion position. In addition, protrusion 2602 of applicator base 2530 has deflected retention arm 2622 sufficiently to release the second end of needle carrier assembly 2508 from holder 2524 in preparation for movement in the proximal direction from the distal insertion position.

[0231] **FIG. 27D** illustrates applicator 2500 during retraction. Spring 2512 remains unloaded, pinning holder 2524 in the distal insertion position. However, leaf spring(s) 2528, still in contact with now-released needle carrier assembly 2508, drive needle carrier assembly 2508 and coupled insertion element 2674 in the proximal direction from the distal insertion position to the proximal retraction position. Retention element(s) 2604 are released from on-skin sensor assembly 160 by virtue of spring 2512 pinning holder 2524, and so on-skin sensor assembly 160 disposed thereunder, in the distal insertion position. In some embodiments, retention element(s) 2604 may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives.

[0232] **FIG. 27E** illustrates applicator 2500 in the proximal retraction position. Leaf spring(s) 2528 have driven needle carrier assembly 2508 and insertion element 2674 in the proximal direction to the proximal retraction position. Applicator 2500 may then be released from the skin of the host, whereby all portions of the applicator 2500 will be removed from the skin of the host except the on-skin sensor assembly 160 and the sensor 138 (e.g., **FIG. 1**) which is now at least partially inserted into the skin of the host.

[0233] **FIGs. 28A-28H** illustrate steps to assemble applicator 2500 of **FIG. 25**, according to some embodiments. **FIG. 28A** illustrates coupling insertion element 2674 to needle carrier

assembly 2508. In some embodiments, insertion element 2674 may be coupled to needle carrier assembly 2508 at an angle that substantially coincides with the circular path insertion element 2674 and needle carrier assembly 2508 traverse during activation. **FIG. 28B** illustrates coupling holder 2524 to needle carrier assembly 2508 by coupling needle carrier assembly 2508 to axle 2614 of holder 2524 and retention element 2622 to holder 2524. **FIG. 28C** illustrates coupling on-skin sensor assembly 160 to holder 2524 and needle carrier assembly 2508 by engaging retention element(s) 2604 of needle carrier assembly 25089 with on-skin sensor assembly 160.

[0234] **FIG. 28D** illustrates inserting activation element 2504 into applicator housing 2502. **FIG. 28E** illustrates coupling a first end of spring 2512 with applicator housing 2502 through an opening in the bottom of applicator housing 2502. **FIG. 28F** illustrates inserting the assembly 2800c resulting from the step(s) illustrated by **FIG. 28C** into applicator housing 2502. In assembly 2800c, shown in **FIG. 28F**, spring 2512 is placed in contact with holder 2524 and holder 2524 is secured by protrusion 2612 of activation element 2504.

[0235] **FIG. 28G** illustrates coupling applicator base 2530 to applicator housing 2502. Axle 2614 of holder 2524 is coupled to applicator base 2530 and leaf spring(s) 2528 are placed in contact with needle carrier assembly 2508. **FIG. 28H** illustrates applicator 2500 in assembled form. At this step, applicator base 2530 may be coupled to applicator housing 2502, for example, via sonic welding, press-fit, snap-fit, adhesive, or any other suitable method of securing plastic materials together.

[0236] **FIG. 29** illustrates an exploded perspective view of yet another applicator 2900 for applying an on-skin sensor assembly to skin 130 of a host, according to some embodiments. Applicator 2900 may include an applicator housing 2902 having an opening at its bottom and configured to house at least one or more mechanisms utilized to apply on-skin sensor assembly 160 to skin 130 of a host.

[0237] Applicator 2900 includes an activation element 2904 configured to activate a drive assembly of applicator 2900. In some embodiments, activation element 2904 may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 2900. Applicator 2900 may further comprise a needle carrier assembly 2908, including an insertion element (see **FIG. 30**) configured to insert sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) into skin 130 of the host. In some embodiments, the insertion element comprises a needle, for

example, an open sided-needle, a needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. In yet other embodiments, insertion element may comprise sensor 138 itself, sufficiently rigid to be inserted partially into skin 130 of the host with minimal or no structural support.

[0238] Applicator 2900 may further comprise a drive assembly 2910 configured to drive the insertion element of needle carrier assembly 2908 in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position. A distal direction may be defined as extending towards an open-ended side of applicator 2900 along a path needle carrier assembly 2908 is configured to travel. The distal direction may also be defined as towards the skin of a user. A proximal direction may be defined as a direction extending in a substantially opposite direction from the distal direction. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element and of needle carrier assembly 2908.

[0239] Drive assembly 2910 may include a rotating drive element 2914 disposed within needle carrier assembly 2908 and configured to rotate with respect to needle carrier assembly 2908 about an axis of rotation 2918 parallel with a centerline of needle carrier assembly 2908. In some embodiments, rotating drive element 2914 is configured to rotate in a plane substantially perpendicular to the proximal direction and the distal direction. In some embodiments, rotating drive element 2914 may comprise a barrel cam. rotating drive element 2914 comprises a ridge 2916 that defines a variable cam path around at least a portion of a circumference of the rotating drive element. Ridge 2916 is configured to slide along a channel (see **FIG. 30**) on an inside surface of needle carrier assembly 2908 as rotating drive element 2914 rotates, thereby driving needle carrier assembly 2908 in the distal direction to the distal insertion position and then in the proximal direction to the proximal retraction position as defined by the variable cam path of ridge 2916.

[0240] Drive assembly 2910 may further include a spring 2912 disposed within rotating drive element 2914. Spring 2912 may be a torsion spring, or any suitable type of spring. Spring 2912 may have a first end 2920 coupled to applicator housing 2902 and a second end 2922 coupled to rotating drive element 2914. Spring 2912 may be disposed coaxially with rotating drive element 2914 and needle carrier assembly 2908. Spring 2920 may be configured to, upon

activation of drive assembly 2910, rotate rotating drive element 2914 in a single direction with respect to needle carrier assembly 2908.

[0241] By virtue of rotating drive element 2914 being configured to rotate with respect to needle carrier assembly 2908, about axis of rotation 2918, and ridge 2916 being restrained to travel in the channel of needle carrier assembly 2908, rotational motion of rotating drive element 2914, caused by spring 2912, is converted into linear, reciprocating motion of needle carrier assembly 2908 and, therefore, insertion element (see **FIG. 30**). More specifically, rotation of rotating drive element 2914 drives insertion element 2908 in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position to the proximal retraction position.

[0242] Applicator 2900 may further include a holder 2924 releasably coupled to needle carrier assembly 2908 via retention element(s) 2980 and configured to guide on-skin sensor assembly 160 while coupled to needle carrier assembly 2908. In some embodiments, retention element(s) 2980 may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives configured to couple on-skin sensor assembly 160 with needle carrier assembly 2908 and/or holder 2924. On-skin sensor assembly 160 may be stripped from holder 2924 and/or needle carrier assembly 2908 once on-skin sensor assembly 160 is disposed on skin 130 of the host.

[0243] **FIG. 30** illustrates a perspective cutaway view of a portion of applicator 2900 of **FIG. 29**, according to some embodiments. **FIG. 30** illustrates at least one protrusion 3024 of needle carrier assembly 2908 configured to slide within tracks (not shown in **FIG. 30**) on an inside surface of applicator housing 2902 (similar to tracks 622a-622c in **FIG. 6**) that define a linear path of travel for needle carrier assembly 2908. **FIG. 30** further illustrates channel 3002 in which ridge 2916 of rotating drive element 2914 is configured to slide as spring 2912 rotates rotating drive element 2914 with respect to needle carrier assembly 2908. **FIG. 30** further illustrates insertion element 3074 coupled to needle carrier assembly 2908.

[0244] In some embodiments, holder 2924 further includes a retention element 3042 configured to engage with a retention element (not shown in **FIG. 30**) of applicator housing 2902, similar to stop element 644 of applicator housing 462 of **FIG. 6**, and immobilize holder 2924 to applicator housing 2902 upon needle carrier assembly 2908 reaching the distal insertion position. Although not shown in **FIG. 30**, holder 2928 may further comprise a protrusion and

applicator housing 2902 may further comprise a protrusion configured to prevent holder 2924 from travelling beyond the distal insertion position in the distal direction, similar to protrusion 652 and protrusion 654 as previously described in connection with **FIG. 6F**.

[0245] **FIG. 31** illustrates a cutaway view of yet another applicator 3100 for an on-skin sensor assembly of an analyte sensor system, according to some embodiments. In some embodiments, applicator 3100 may include an applicator housing 3102 configured to house one or more mechanisms for applying on-skin sensor assembly 160 to skin 130 of a host. Applicator 3100 may further comprise a base 3130 coupled to applicator housing 3102 and configured to form a bottom of applicator 3100.

[0246] Applicator 3100 further includes an activation element (not shown in **FIG. 31**) configured to activate a drive assembly 3110 of applicator 3100. In some embodiments, the activation element may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 3100. In addition, the activation element of applicator 3100 may be disposed in any location and orientation with respect to applicator housing 3102, e.g., a top, any portion of a side, or bottom of applicator housing 3102 and/or at any angle with respect to the portion of applicator housing 2102 in which the activation element is disposed. Applicator 3100 may further comprise a needle carrier assembly 3108, including an insertion element 3174 releasably coupled to on-skin sensor assembly 160 and configured to insert sensor 138 of on-skin sensor assembly 160 (e.g., **FIG. 1**) into skin 130 of the host. In some embodiments, the insertion element comprises a needle, for example, an open sided-needle, a needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, deflected-tip or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. In yet other embodiments, insertion element may comprise sensor 138 itself, sufficiently rigid to be inserted partially into skin 130 of the host with minimal or no structural support,

[0247] Drive assembly 3110 may be configured to drive insertion element 3174 of needle carrier assembly 3108 in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position. Drive assembly 3110 may include a guide member 3138, a spring 3112, a hub 3132 and a reverse toggling element 3136. guide member 3138 may be coupled to at least one of applicator housing 3102 and base 3130 at a first end and/or a second end, respectively. Spring 3112 may be disposed around guide

member 3138 such that guide member 3138 extends substantially along a centerline of spring 3112. Spring 3112 may be any suitable type of spring, e.g., a compression spring, and may have a first end coupled to base 3130 and a second end coupled to a hub 3132, which is disposed on and configured to travel along guide member 3138. Spring 3120 may be configured to, upon activation of drive assembly 3110, drive hub 3132 in the proximal direction along guide member 3138, as shown by the arrow. Reverse toggling element 3136 may function substantially as a lever with a fulcrum at or near its midpoint, rotatably coupled to base 3130 or applicator housing 3102. A first end of reverse toggling element 3136 may be in contact with a protrusion 3134 of hub 3132 for at least a first portion of travel of hub 3132 in the proximal direction and a second end of reverse toggling element 3136 may be in contact with needle carrier assembly 3108. Insertion assembly 3108 may be slideably coupled to guide member 3138 on the side of hub 3132 opposite spring 3112.

[0248] In operation, upon activation of drive assembly 3110, spring 3112 drives hub 3132 along guide member 3138 in the proximal direction. For a first portion of travel along guide member 3138, protrusion 3134 of hub 3132 is in contact with the first end of reverse toggling element 3136, causing the second end of reverse toggling element 3136 to drive needle carrier assembly 3138, and so insertion element 3174 and on-skin sensor assembly 160, in the distal direction. After the first portion of travel along guide member 3138, protrusion 3134 of hub 3132 will clear the first end of reverse toggling element 3136 and make contact with the portion of needle carrier assembly 3138 slideably coupled with guide member 3138. At this point, needle carrier assembly 3108, insertion element 3174 and on-skin sensor assembly 160 are in the distal insertion position. For a second portion of travel along guide member 3138 in the proximal direction, hub 3132, still driven by spring 3112, drives needle carrier assembly 3108, and so insertion element 3174, in the proximal direction from the distal insertion position to the proximal retraction position. In this way, drive assembly 3110 converts linear motion of spring 3112 in a single direction, e.g., the proximal direction, into reciprocating linear motion in the distal direction and then the proximal direction.

[0249] **FIG. 32A** illustrates an exploded perspective view of yet another applicator 3200 for an on-skin sensor assembly of an analyte sensor system, according to some embodiments. Applicator 3200 may include an applicator housing 3202 configured to house at least one or more mechanisms utilized to apply the on-skin sensor assembly 160 to skin 130 of a host.

Applicator 3200 may further include a base 3230 coupled to a bottom opening of applicator housing 3202. Base 3230 defines a bottom surface of applicator 3200 and a plane for application of on-skin assembly 160 to skin 130 of a host.

[0250] Applicator 3200 includes an activation element 3204 configured to activate a drive assembly of applicator 3200. In some embodiments, activation element 3204 may be a button, a switch, a toggle, a slide, a trigger, a knob, a rotating member, a component that deforms and/or flexes or any other suitable mechanism for activating a drive assembly of applicator 460.

[0251] Applicator 3200 may further comprise a needle carrier assembly 3208, including an insertion element 3274 configured to insert sensor 138 of on-skin sensor assembly 160 into skin 130 of the host (e.g., **FIG. 1**). In some embodiments, the insertion element comprises a needle, for example, an open sided-needle, a needle with a deflected-tip, a curved needle, a polymer-coated needle, a hypodermic needle, or any other suitable type of needle or structure, as will be described in more detail in connection with at least **FIGs. 47-50**. In yet other embodiments, insertion element may comprise sensor 138, sufficiently rigid to be inserted partially into skin 130 of the host with minimal or no structural support.

[0252] Applicator 3200 may further include a holder 3224 releasably coupled to needle carrier assembly 3208 and configured to guide on-skin sensor assembly 160 while coupled to needle carrier assembly 3208. As will be described in more detail below, on-skin sensor assembly 160 may be stripped from holder 3224 and needle carrier assembly 3208 once on-skin sensor assembly 160 is disposed on skin 130 of the host.

[0253] Applicator 3200 may further comprise a drive assembly configured to drive insertion element 3274 and needle carrier assembly 3208 in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position to the proximal retraction position. Drive assembly 3210 may include a first spring 3212 and a second spring 3228. First spring 3212 may be a compression spring, or any suitable type of spring, and may have a first end coupled to applicator housing 3202 and a second end coupled to holder 3224. First spring 3212 is configured to, upon activation of drive assembly 3210, drive holder 3224, and also coupled needle carrier assembly 3208, insertion element 3274 and on-skin sensor assembly 160, in the distal direction to the distal insertion position. Substantially at the distal insertion position, needle carrier assembly 3208 may decouple from holder 3224 and on-skin sensor assembly 160.

[0254] Second spring 3228 may be a compression spring, or any suitable type of spring, and may have a first end coupled to holder 3224 and a second end coupled to needle carrier assembly 3208. Second spring 3228 is configured to drive needle carrier assembly 3208, and also insertion element 3274, in the proximal direction from the distal insertion position to the proximal retraction position. In some embodiments, first spring and/or second spring can be preloaded, partially loaded, or unloaded.

[0255] **FIG. 32B** illustrates an exploded perspective view 3250 of needle carrier assembly 3208 coupled to insertion element 3274, second spring 3228, holder 3224 and on-skin sensor assembly 160.

[0256] **FIG. 33A-33E** illustrate perspective cutaway views of several features of applicator 3200 of **FIG. 32**, according to some embodiments. **FIG. 33A** illustrates a perspective cutaway view of the entire applicator 3200, including applicator housing 3202, activation element 3204, first spring 3212, needle carrier assembly 3208 coupled to insertion element 3274, holder 3224 coupled to on-skin sensor assembly 160, and base 3230. Each of these components may have functionality as previously described in connection with at least **FIG. 32**.

[0257] **FIG. 33B** illustrates a magnified perspective cutaway view of a retention element 3312 of holder 3224 releasably coupled to application housing 3202. Retention element 3312 is configured to prevent holder 3224 from traveling in the distal direction and, therefore, spring 3212 from unloading. Activation mechanism 3204, when activated, is configured to deflect retention element 3312 sufficiently to decouple it from applicator housing 3202, thereby freeing holder 3224 to travel in the distal direction, driven by spring 3212.

[0258] **FIG. 33C** illustrates a magnified perspective cutaway view of a retention element 3342 of needle carrier assembly 3208 configured to releasably couple needle carrier assembly 3208 to holder 3224. As shown, retention element 3342 may have a sloped surface configured to come in contact with a protrusion (not shown in **FIG. 33**) of the applicator housing 3202 or base 3230 (not shown in **FIG. 33**) that is configured to deflect retention element 3342 sufficiently to decouple needle carrier assembly 3208 from holder 3224 when needle carrier assembly 3208 is at or near the distal insertion position.

[0259] **FIG. 33D** illustrates a perspective view of a plurality of retention elements 3372a, 3372b of needle carrier assembly 3208 configured to pass through holder 3224 and releasably couple on-skin sensor assembly 160 to holder 3224 and to needle carrier assembly 3208. As

previously described, at the distal insertion position, deflected retention element 3342 decouples needle carrier assembly 3208 from holder 3224, allowing second spring 3228 to drive needle carrier assembly 3208 in the proximal direction. As needle carrier assembly 3208 is driven in the proximal direction, retention elements 3372a, 3372b detach from on-skin sensor assembly 160. Although two retention elements are illustrated, any number of retention elements are contemplated. In some embodiments, retention element(s) 3372a, 3372b may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives configured to couple on-skin sensor assembly 160 with needle carrier assembly 3208 and/or holder 3224. Moreover, alternative mechanisms that may perform such retention and release actions are further described in connection with at least **FIGs. 47-50** below.

[0260] **FIG. 33E** illustrates a perspective cutaway view of a retention element 3346 of holder 3224 and a retention element 3348 of applicator housing 3202 configured to immobilize needle carrier assembly 3208 to holder 3346 upon needle carrier assembly 3208 reaching the distal insertion position. This interaction immobilizes insertion element 3274 in the proximal retraction position, thereby ensuring the end of insertion element 3274 is not exposed out the bottom of applicator 3200.

[0261] A brief description of the operation of applicator 3200 follows with respect to **FIGs. 34A-34F**, which illustrate several perspective views of the applicator of **FIG. 32** during operation, according to some embodiments.

[0262] **FIG. 34A** illustrates a state of applicator 3200 at activation. Activation element 3204 is illustrated in the process of being activated, having been pushed down by a user, for example. Activation element 3204 deflects retention element 3312 such that holder 3224 is not prevented from traveling in the distal direction. Holder 3224, needle carrier assembly 3208, insertion element 3274, first spring 3212 and second spring 3228 are all shown in pre-activation positions.

[0263] **FIG. 34B** illustrates applicator 3200 during activation. Activation element 3204 is illustrated in the activated position. Spring 3212 is driving holder 3224, and also needle carrier assembly 3208, insertion element 3274, and on-skin sensor assembly 160, in the distal direction toward the distal insertion position.

[0264] **FIG. 34C** illustrates applicator 3200 during activation, as needle carrier assembly 3208 approaches the distal insertion position. Activation element 3204 is illustrated in the

activated position. Insertion assembly 3208, insertion element 3274, holder 3224 and on-skin sensor assembly 160 are driven in the distal direction to the distal insertion position. At or near this distal insertion position, at least a portion of insertion element 3274 as well as at least a portion of sensor 138 of on-skin sensor assembly 160 may be inserted into the skin of the host. At this position, retention element 3342 is deflected by a portion of applicator housing 3302 or base 3230, thereby decoupling needle carrier assembly 3208 from holder 3224.

[0265] **FIG. 34D** illustrates applicator 3200 during activation. Activation element 3204 is illustrated in the activated position. Second spring 3228 drives needle carrier assembly 3208 and insertion element 3274 in the proximal direction from the distal insertion position. Although not shown in **FIG. 34D**, once needle carrier assembly reaches the proximal retraction position, retention elements 3346 and 3348 may be engaged with one another immobilizing needle carrier assembly 3208 and insertion element 3274 in the proximal retraction position, thereby maintaining insertion element 3274 in a safe, retracted position.

[0266] **FIG. 35A-35C** illustrate several cross-sectional views of an on-skin sensor assembly retention mechanism of applicator 3200 of **FIG. 32**, according to some embodiments. The retention mechanism described in connection with **FIGs. 35A-35C** is similar to the retention mechanism previously described in connection with **FIGs. 6A-6H**. **FIG. 35A** illustrates the retention mechanism while applicator 3200 is in the pre-activated state. Retention element 3372a is illustrated as a portion of holder 3224 and configured to releasably couple on-skin sensor assembly 160 to holder 3224 as needle carrier assembly 3208 travels in the distal direction to the distal insertion position, and to decouple on-skin sensor assembly 160 from holder 3224 as needle carrier assembly 3208 travels in the proximal direction from the distal insertion position towards the proximal retraction position. Specifically, retention element 3372a may comprise a first end 3376a and a second end 3378a. The second end may be releasably coupled to on-skin sensor assembly 160 in the pre-activation state. As previously stated, retention element(s) 3372a, 3372b may comprise snap fits, friction fits, interference features, elastomeric grips and/or adhesives configured to couple on-skin sensor assembly 160 with needle carrier assembly 3208 and/or holder 3224. **FIG. 35A** further illustrates applicator housing 3202 comprising an optional reinforcing element 3510 configured to prevent lateral motion of retention element 3372a in the proximal starting position, thereby supporting releasable coupling of second end 3378a of retention element 3372a with on-skin sensor assembly 160.

[0267] **FIG. 35B** illustrates applicator 3200 in the distal insertion position after activation. As needle carrier assembly 3208 travels in the distal direction to the distal insertion position, retention element 3342 of needle carrier assembly 3208 is released from holder 3224. The second end of retention element 3372a may still be releasably coupled to on-skin sensor assembly 160. **FIG. 35B** further illustrates optional reinforcing element 3510 as no longer being in physical contact with retention element 3372a in the distal insertion position, thereby allowing for the uncoupling of second end 3378a of retention element 3372a from on-skin sensor assembly 160.

[0268] **FIG. 35C** illustrates applicator 3200 where needle carrier assembly 3208 is moving in the proximal direction from the distal insertion position. Since retention element 3342 of needle carrier assembly 3208 was uncoupled from holder 3224 at the distal insertion position, as needle carrier assembly 3208 travels back in the proximal direction, needle carrier assembly 3208 separates from holder 3224. As needle carrier assembly 3208 travels in the proximal direction, first end 3376a of retention element 3372a is deflected by needle carrier assembly 3208, thereby decoupling second end 3378a of retention element 3372a from on-skin sensor assembly 160. **FIG. 35C** further illustrates optional reinforcing element 3510 as no longer being in physical contact with retention element 3372a in the distal insertion position.

[0269] **FIG. 36A-36C** illustrate several cross-sectional views of another on-skin sensor assembly retention mechanism of applicator 3200 of **FIG. 32**, according to some embodiments. **FIG. 36A** illustrates the retention mechanism while applicator 3200 is in the pre-activated state. Retention element 3372a is illustrated as a portion of needle carrier assembly 3208 and is configured to releasably couple on-skin sensor assembly 160 to holder 3224 as needle carrier assembly 3208 travels in the distal direction to the distal insertion position, and to decouple on-skin sensor assembly 160 from holder 3224 as needle carrier assembly 3208 travels in the proximal direction from the distal insertion position towards the proximal retraction position. Specifically, retention element 3372a may releasably couple on-skin sensor assembly 160 as needle carrier assembly 3208 travels in the distal direction to the distal insertion position. **FIG. 36A** further illustrates applicator housing 3202 comprising an optional reinforcing element 3610 configured to prevent lateral motion of retention element 3372a and/or retention element 3342 in the proximal starting position, thereby supporting releasable coupling of retention element 3372a with on-skin sensor assembly 160.

[0270] **FIG. 36B** illustrates applicator 3200 at the distal insertion position. Retention element 3342 of needle carrier assembly 3208 is uncoupled from holder 3224 at the distal insertion position, retention element 3224 being deflected by a portion of applicator housing 3202 or an applicator base of applicator housing 3202 sufficient for retention element 3224 to clear a stop element of needle carrier assembly. Accordingly, needle carrier assembly 3208 separates from holder 3224 as needle carrier assembly 3208 travels back in the proximal direction by a force provided by spring 3228. Rather than being physically deflected in orientation as needle carrier assembly 3208 travels in the proximal direction, retention element 3372a is formed to be easily deflected or deformed simply by the separation of holder 3224 from needle carrier assembly 3208. **FIG. 36B** further illustrates optional reinforcing element 3610 as no longer being in physical contact with retention element 3372a and/or retention element 3342 in the distal insertion position, thereby allowing for the uncoupling of retention element 3372a from on-skin sensor assembly 160 and/or the uncoupling of holder 3224 from needle carrier assembly 3208.

[0271] **FIG. 36C** illustrates needle carrier assembly 3208 moving in the proximal direction from the distal insertion position of **FIG. 36B**. As shown, retention element 3372a has been released from on-skin sensor assembly 160 by separation of needle carrier assembly 3208 from holder 3224, and needle carrier assembly 3208 is driven in the proximal direction by a force provided by spring 3228. **FIG. 36C** further illustrates optional reinforcing element 3610 as no longer being in physical contact with retention element 3372a and/or retention element 3342 in the proximal retracted position.

[0272] **FIG. 37A-37C** illustrate several cross-sectional views of yet another on-skin sensor assembly retention mechanism of applicator 3200 of **FIG. 32**, according to some embodiments. **FIG. 37A** illustrates applicator 3200 in the pre-activated position. Retention element 3372a is illustrated in **FIG. 37A** as an integral portion of holder 3208 and is configured to releasably couple on-skin sensor assembly 160 to holder 3224 as needle carrier assembly 3208 travels in the distal direction to the distal insertion position, and to decouple on-skin sensor assembly 160 from holder 3224 as needle carrier assembly 3208 travels in the proximal direction from the distal insertion position towards the proximal retraction position. Specifically, retention element 3372a may releasably couple on-skin sensor assembly 160 as needle carrier assembly 3208 travels in the distal direction to the distal insertion position. **FIG. 37A** further illustrates

applicator housing 3202 comprising an optional first reinforcing element 3710 configured to prevent lateral motion of retention element 3342 in the proximal retracted position. **FIG. 37A** further illustrates needle carrier 3208 comprising an optional second reinforcing element 3712 configured to prevent lateral motion of retention element 3372a, thereby supporting releasable coupling of retention element 3372a with on-skin sensor assembly 160.

[0273] **FIG. 37B** illustrates needle carrier assembly 3208 in the distal insertion position. Retention element 3342 of needle carrier assembly 3208 is uncoupled from holder 3224 at the distal insertion position. Accordingly, needle carrier assembly 3208 separates from holder 3224 as needle carrier assembly 3208 travels back in the proximal direction under influence of a force provided by spring 3228 as spring 3228 unloads, pushing against holder 3224 and needle carrier assembly 3208. **FIG. 37B** further illustrates optional first reinforcing element 3710 as no longer being in physical contact with retention element 3342 in the distal insertion position, thereby allowing for the uncoupling of holder 3224 from needle carrier assembly 3208. Optional second reinforcing element 3712 is still illustrated as being in physical contact with retention element 3372a in the distal insertion position.

[0274] **FIG. 37C** illustrates needle carrier assembly as it begins to travel in the proximal direction, after retention element 3372a of needle carrier assembly 3208 is uncoupled from holder 3224. Rather than being physically deflected in orientation as needle carrier assembly 3208 travels in the proximal direction, as in **FIGs. 35A-35C**, retention element 3372a detaches from on-skin sensor assembly 160 simply by the user removing applicator 3200 from the skin. In some embodiments, an adhesive patch that holds on-skin sensor assembly 160 to the skin of the host provides sufficient bonding strength to decouple on-skin sensor assembly 160 from the skin of the host when applicator 3200 is removed from the skin. **FIG. 37C** further illustrates optional first reinforcing element 3710 as no longer being in physical contact with retention element 3372a in the proximal retracted position, thereby supporting uncoupling of retention element 3372a from on-skin sensor assembly 160.

[0275] **FIG. 38** illustrates a perspective view of an applicator 3800 similar to those shown in **FIG. 32**, including an activation element 3804 on a side of an applicator housing 3802, according to some embodiments. Applicator 3800 may have substantially the same features as either applicator 3200 of **FIG. 32**, except that activation element 3804 is located on a side of applicator housing 3802, rather than on a top of the applicator housing. Such an arrangement

may provide for an applicator having a reduced height compared to top-activated applicators, though potentially having an increased width or diameter compared to the top-activated applicators.

[0276] **FIG. 39** illustrates a cutaway view of a portion of applicator 3800 of **FIG.** 38, according to some embodiments. Activation element 3804 may be configured to, upon activation, deflect a retention element 3902 of holder 3824 configured to prevent holder 3824 from traveling in the distal direction. All other features of applicator 3800 not discussed may be substantially as previously described for either applicator 3200 of **FIG. 32**.

[0277] **FIGs. 40A-40G** illustrate several perspective views of an assembly process for the applicator of **FIG. 32**, according to some embodiments. **FIG. 40A** illustrates inserting second spring 3228 into holder 3224. **FIG. 40B** illustrates next inserting insertion element 3274 into needle carrier assembly 3208 and then inserting insertion element 3274 into needle carrier assembly 3208 into holder 3224. In some embodiments, inserting insertion element 3274 into needle carrier assembly 3208 into holder 3224 pre-compresses second spring 3228. **FIG. 40C** illustrates coupling on-skin sensor assembly 160 to at least one of holder 3224 and needle carrier assembly 3208 by coupling retention elements (not shown in **FIG. 40C**) of holder 3224 or of needle carrier assembly 3208 to attachment points (not shown in **FIG. 40C**) of on-skin sensor assembly 160.

[0278] **FIG**. **40D** illustrates coupling activation element 3204 to applicator housing 3202. In **FIG. 40D**, activation element 3204 is coupled on a top of applicator housing 3202. In some embodiments, activation element 3204 may be pressed into an opening of applicator housing 3202 configured to receive activation element 3204. However, in other embodiments, applicator housing 3202 may accommodate activation element 3204 in other locations, for example, an upper, medial or lower side of applicator housing. **FIG. 40E** illustrates inserting first spring 3212 into applicator housing 3202. **FIG. 40F** illustrates inserting the assembly described in **FIG. 40C** (comprising holder 3224, second spring 3228, needle carrier assembly 3208, insertion element 3274 and on-skin sensor assembly 160) into applicator housing 3202. In some embodiments, the act of inserting the assembly described in **FIG. 40C** pre-compresses first spring 3212. **FIG. 40G** illustrates coupling base 3230 to applicator housing 3202.

<u>On-Skin Sensor Assembly Retention Mechanisms</u>

[0279] In some embodiments of applicators described herein, on-skin sensor assembly 160 is held in place during at least travel in the distal direction to the distal insertion position. In some such embodiments, on-skin sensor assembly 160 is then released or decoupled from a portion of the applicator during application to the skin of the host so that a needle carrier assembly and insertion element may travel back in the proximal direction. **FIGs. 41A-45** illustrate several alternative retention mechanisms that may be utilized in any of the applicators described herein.

[0280] **FIGs. 41A-41B** illustrate an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments. The retention mechanism illustrated by **FIGs. 41A-41B** may be considered a first on-skin sensor assembly retention configuration, and is similar to the retention mechanism previously described in connection with **FIG. 5**.

[0281] **FIG. 41A** illustrates a retention mechanism in a state where on-skin sensor assembly 160 is retained, while **FIG. 41B** illustrates the retention mechanism in a state where on-skin sensor assembly 160 is decoupled.

[0282] **FIG. 41A** illustrates retention elements 4172a, 4172b of a holder 4124 configured to releasably couple on-skin sensor assembly 160 to holder 4124 as needle carrier assembly 4108 (and so insertion element 4172, holder 4124, and on-skin sensor assembly 160) travels in the distal direction to the distal insertion position. Specifically, retention elements 4172a, 4172b may each comprise a first end 4176a, 4176b, a second end 4178a, 4178b, and a pivot point 4180a, 4180b. First end 4176a, 4176b is immobilized in a respective guide 4174a, 4174b of needle carrier assembly 4108 and each of retention elements 4172a, 4172b is immobilized against interference points 4182a, 4182b of needle carrier assembly 4108, thereby releasably coupling and immobilizing second end 4178a, 4178b to attachment points 4162a, 4162b of on-skin sensor assembly 160 as needle carrier assembly 4108 travels in the distal direction to the distal insertion position. In some embodiments, the profile of slots 4174a, 4174b may be such that the sides of slots 4174a, 4174b exert a force on first ends 4176a, 4176b of retention elements 4172a, 4172b sufficient to hold second ends 4178a, 4178b of retention elements 4172a, 4172b in engagement with attachment points 4162a, 4162b of on-skin sensor assembly 160. Although two retention elements are illustrated, any number of retention elements are contemplated.

[0283] **FIG. 41B** illustrates the retention mechanism as needle carrier assembly 4108 and insertion element 4174 travel in the proximal direction from the distal insertion position to the proximal retraction position. As needle carrier assembly 4108 travels back in the proximal direction, needle carrier assembly 4108 separates from holder 4124, thereby removing first ends 4176a, 4176b of retention elements 4172a, 4172b from respective slots 4174a, 4174b, allowing first ends 4176a, 4176b to deflect inward and second ends 4178a, 4178b of retention elements 4172a, 4172b to deflect outward from attachment points 4162a, 4162b of on-skin sensor assembly 160 as retention elements 4172a, 4172b rotate about pivot points 4180a, 4180b.

[0284] **FIGs. 42A-42B** illustrate an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments. The retention mechanism illustrated by **FIGs. 42A-42B** may be considered a second on-skin sensor assembly retention configuration, and is similar to the retention mechanism previously described in connection with **FIG. 36**. **FIG. 42A** illustrates a retention mechanism in a state where on-skin sensor assembly 160 is retained, while **FIG. 42B** illustrates the retention mechanism in a state where on-skin sensor assembly 160 is decoupled.

[0285] **FIG. 42A** illustrates retention elements 4272a, 4272b as portions of needle carrier assembly 4208 that pass through or around needle carrier assembly 4208, rather than as portions of holder 4224. Retention elements 4272a, 4272b are configured to releasably couple on-skin sensor assembly 160 to holder 4228 as needle carrier assembly 4208 (and so an insertion element, holder 4224, and on-skin sensor assembly 4224) travels in the distal direction to the distal insertion position.

[0286] **FIG. 42B** illustrates the retention mechanism as needle carrier assembly 4208 and insertion element 4274 travel in the proximal direction from the distal insertion position to the proximal retraction position. As needle carrier assembly 4208 travels in the proximal direction, needle carrier assembly 2508 separates from holder 4224 and retention elements 4272a, 4272b are uncoupled from respective attachment points 4262a, 4262b of on-skin sensor assembly 160. Rather than being physically deflected in orientation as needle carrier assembly 4208 travels in the proximal direction, as described for retention elements 4172a, 4172b of **FIGs. 41A-41B**, retention elements 4272a, 4272b are pulled out of attachment points 4262a, 4262b by the energy of the retraction.

[0287] **FIGs. 43A-43B** illustrate an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments. The retention mechanism illustrated by **FIGs. 43A-43B** may be considered a passive snap design. **FIG. 43A** illustrates a retention mechanism in a state where on-skin sensor assembly 160 is retained, while **FIG. 43B** illustrates the retention mechanism in a state where on-skin sensor assembly 160 is decoupled.

[0288] **FIG. 43A** illustrates retention elements 4372a, 4372b as portions of a holder 4324. Retention elements 4372a, 4372b are configured to releasably couple on-skin sensor assembly 160 to holder 4324 as needle carrier assembly 4308 (and so an insertion element, holder 4324, and on-skin sensor assembly 4324) travels in the distal direction to the distal insertion position. **FIG. 43A** further illustrates protrusions 4380a, 4380b of needle carrier assembly 4308 configured to physically contact retention elements 4372a, 4372b of holder 4324 thereby preventing retention elements 4372a, 4372b from disengaging from on-skin sensor assembly 4324 while needle carrier assembly 4308 is in contact with holder 4324.

[0289] **FIG. 43B** illustrates the retention mechanism as needle carrier assembly 4308 travels in the proximal direction from the distal insertion position to the proximal retraction position. As needle carrier assembly 4308 travels in the proximal direction, needle carrier assembly 4308 separates from holder 4324. Although not shown in **FIGs. 43A-43B**, holder 4324 may be immobilized to an applicator housing or base by one or more retention elements, similar to retention elements 642, 644 of **FIG. 6E**. Accordingly, retention elements 4372a, 4372b may be uncoupled from respective attachment points 4362a, 4362b of on-skin sensor assembly 160 as the applicator is removed from the skin of the host. In some embodiments, an adhesive patch that holds on-skin sensor assembly 160 to the skin of the host provides sufficient bonding strength to decouple on-skin sensor assembly 160 from the skin of the host when the applicator is removed from the skin.

[0290] **FIG. 44** illustrates another portion of an exemplary on-skin sensor assembly retention mechanism of an applicator for an analyte sensor system, according to some embodiments. **FIG. 44** illustrates a needle carrier assembly 4408, a holder 4424, and on-skin sensor assembly 160. Contrary to several previous embodiments of retention mechanisms for on-skin sensor assembly 160, needle carrier assembly 4408 comprises at least one retention element 4472a and holder 4424 comprises at least one alignment element 4473a, in which retention

element 4472a is configured to releasably couple to on-skin sensor assembly 160, and alignment element 4473a is configured to align on-skin sensor assembly 160 within the applicator. This distribution of retention elements between both a needle carrier assembly and a holder may be implemented for any on-skin sensor assembly retention mechanism described herein.

[0291] **FIGs. 45** and **46** illustrate portions of exemplary on-skin sensor assembly retention mechanisms of an applicator for an analyte sensor system, according to some embodiments. **FIGs. 45** and **46** illustrate a needle carrier assembly 4508, 4608, a rotating drive element 4514, 4614 similar to that previously described in connection with **FIG. 5**, and on-skin sensor assembly 160. Accordingly, the retention mechanisms of **FIGs. 45** and **46** may function similarly to that described in **FIG. 5**. Rotating drive element 4514, 4614 may be a wheel cam and may comprise a cam lobe 4518 (e.g., a ramp or protrusion, not shown in **FIG. 46**, see **FIG. 45**) disposed along at least a portion of a circumference of rotating drive element 4514, 4614. In **FIG. 45**, as rotating drive element 4514 is rotated, protrusion 4518 may travel alongside needle carrier assembly 4508 and come into contact with and increasingly apply a force to on-skin sensor assembly 160 such that on-skin sensor assembly 160 decouples from needle carrier assembly 4508. In **FIG. 46**, as rotating drive element 4614 is rotated, the protrusion may travel at least partially through a guide or slot 4620 in needle carrier assembly 4608 and come into contact with and increasingly apply a force to on-skin sensor assembly 160 such that on-skin sensor assembly 160 decouples from needle carrier assembly 4608. In this way, rotating drive element 4514, 4614 may serve both to drive needle carrier assembly 4508, 4608 in the distal and proximal directions, as previously described in connection with **FIG. 5**, and to release on-skin sensor assembly 160 upon deposition to the skin of the host.

[0292] In some embodiments, on-skin sensor assembly retention mechanisms may incorporate features to couple an on-skin sensor assembly to the needle carrier assembly and/or the holder. Methods of coupling on-skin sensor assembly are described in U.S. Patent Application No. 15/387088, which is incorporated herein by reference it its entirety. For non-limiting example, on-skin sensor assembly retention mechanisms may include a frangible release (e.g. **FIGS. 137-140**), a frangible elastomer (e.g. **FIGS. 134-136**), a releasable adhesive (e.g. **FIG. 123-125**), or a releasable friction-fit coupling (e.g. **FIG. 126-133**).

[0293] For example, a frangible release can be implemented in the current embodiments by a structure attached between an on-skin sensor assembly (e.g. 160), a holder (e.g. 524), a

needle carrier (e.g. 508), and/or an applicator housing (e.g. 502). The frangible component may include features such has a weakened portion or a portion designated to fracture during release of the on-skin sensor assembly from the applicator. Frangible components configured to fracture may include patch material (e.g. spun lace) or molded components (e.g. ABS, PC, polymer, elastomeric polymer, etc.).

[0294] For example, a releasable adhesive can be implemented in the current embodiments by a releasable adhesive releasably attached between an on-skin sensor assembly (e.g. 160), a holder (e.g. 524), a needle carrier (e.g. 508), and/or an applicator housing (e.g. 502). The releasable adhesive may consist of a double sided adhesive tape, a glue, or a hot melt polymer. The releasable adhesive is configured to detach during release of the on-skin sensor assembly from the applicator via an applicator mechanism (e.g. retraction mechanism) or user force.

[0295] For example, a releasable friction-fit coupling can be implemented in the current embodiments by a surface contact between an on-skin sensor assembly (e.g. 160), a holder (e.g. 524), a needle carrier (e.g. 508), and/or an applicator housing (e.g. 502). The releasable friction-fit coupling may consist of a rigid or elastomeric material (e.g. silicone, TPE, TPU, rubber, etc.) or a combination thereof. The coupled components (e.g. on-skin sensor assembly 160 and holder 524) have a frictional material interaction (e.g. interference fit, deformable fit, etc.). The releasable friction-fit coupling is configured to detach during release of the on-skin sensor assembly from the applicator via an applicator mechanism (e.g. retraction mechanism) or user force.

Insertion Element Embodiments

[0296] Several embodiments of an insertion element, as previously described herein, will now be described in connection with at least **FIGs. 47-50**, in which the insertion element is illustrated as being a needle.

[0297] **FIG. 47** illustrates a cross-sectional view of a kinked needle 4774 for use in an applicator for an analyte sensor system, according to some embodiments. Kinked needle 4774 may have at least two substantially straight portions 4790, 4792 with a bend 4796 between each substantially straight portion such that an angle 4796 between the substantially straight portions

is substantially optimized to reduce lateral motion of a tip of needle 4774 through the skin of the host as needle 4774 traces an arc during activation.

[0298] **FIGs. 48A-48B** illustrate a cross-section and a plan view, respectively, of a flared open-sided needle 4874 for use in an applicator for an analyte sensor system, according to some embodiments. Although **FIGs. 48A-48B** illustrate open-sided needle 4874 having a C-shaped cross-section, the open-sided needle 4874 may have any shaped cross-section, e.g., a C-shape, a U-shape, a V-shape. **FIG. 48A** illustrates a cross-section of an open-sided needle 4874 having at least one flared edge 4876. For example, flared edge 4876 may be flared in a lateral direction from a longitudinal centerline of open-sided needle 4874. Such a flared edge 4876 may prevent or substantially reduce the incidence of damage to sensor 138 (e.g., **FIG. 1**) caused by sharp edges of the open-sided needle coming in contact with sensor 138 before or during insertion into the skin of a host.

[0299] **FIG. 48B** illustrates a plan view of open-sided needle 4874. Open-sided needle 4874 is illustrated as formed with an end opposite its tip having a needle skirt 4878. Needle skirt 4878 may aid directing sensor 138 into the needle lumen to assist with loading of sensor 138 and/or reduce the opportunity for damage of sensor 138 during use and/or loading.

[0300] **FIG. 49** illustrates a perspective view of a deflected-tip needle 4974 for use in an applicator for an analyte sensor system, according to some embodiments. deflected-tip needle 4974 may comprise a substantially straight shaft having a substantially curved tip 4980, such that an angle of entry of deflected-tip needle 4974 is offset from the substantially straight shaft. Such an angle offset of the substantially curved tip 4980 may be particularly useful for reducing tissue damage and insertion resistance for applicators such as applicator 2500, as previously described in connection with **FIGs. 25-28H**, that have an insertion path for the insertion element that is a substantially curved path. The substantially curved tip 4980 may steer deflected-tip needle 4974 in the direction of the substantially curved insertion path, thereby reducing tissue damage caused by lateral movement of the needle with respect to its direction of extension. **FIG. 49** illustrates a magnified view 4950 of the curved tip 4980.

[0301] **FIG. 50** illustrates a curved needle 5074 for use in an applicator for an analyte sensor system, according to some embodiments. As shown, curved needle 5074 has a profile that is substantially curvilinear. Such a curvilinear profile may be particularly useful for reducing tissue damage and insertion resistance for applicators such as applicator 2500, as previously

described in connection with **FIGs. 25-28H**, that have an insertion path for the insertion element that is a substantially curved path. The substantially curvilinear profile of needle 5074 may reduce tissue damage caused by lateral movement of the needle with respect to its direction of extension. In some embodiments, the curvilinear profile of needle 5074 may substantially track or trace the insertion path for the applicator, thereby substantially eliminating, or at least greatly reducing, lateral movement of the needle with respect to the skin of the host. In some embodiments, sensor 138 of on-skin sensor assembly 160 may have a curvilinear profile also, thereby allowing sensor 138 to rest within a portion of curved needle 5074.

[0302] In yet other embodiments, the insertion element, for example a C-needle may have at least a portion coated with a polymer that prevents damage to the tissue of the host and/or to the sensor wire. Such a polymer may include, but is not limited to, cyanoacrylate, epoxy, elastomeric polymers, urethanes or any other suitable polymer.

[0303] In some embodiments, at least a sensing portion of sensor 138 may be coated with AgCl to improve the reference capacity of sensor 138. However, AgCl is a catalyst for corroding the metal in the insertion element (e.g., open-sided needle). Accordingly, an AgCl coating on sensor 138 that comes into contact with the insertion element may be undesirable. One method of decreasing corrosion of sensor 138 and/or the insertion element is to selectively remove or substantially decrease the content of AgCl on at least a proximal end of sensor 138 without substantially affecting the region of sensor 138 that is inserted into the skin of the host. This may be accomplished by exposing the desired portion of sensor 138 to a single frequency or multiple frequencies of ultraviolet radiation for a predetermined length of time and at a predetermined intensity. Such a process may be performed at any time, for example, during the skiving or singulation process. Another method of removing AgCl is to expose the desired portion of sensor 138 to an ammonia (NH_3) rinse at a desired concentration and for a desired length of time.

Sharp Protection

[0304] **FIGs. 51A-51B** illustrate cutaway views of a needle hub of an applicator for an analyte sensor system, according to some embodiments. **FIG. 51A** illustrates a needle hub 5104, an insertion element 5174, a needle guard 5102, a spring 5174, and a base 5130 of the applicator. First needle hub 5104 may be fixed to a portion other than a tip of insertion element 5174. Second needle hub 5102 may be configured to encapsulate the tip of insertion element 5174 and

may comprise a material that insertion element 5174 may pierce during deployment and/or may include an aperture or hole through which insertion element 5174 may pass. Spring 5106 is configured to keep a predetermined spacing between needle hub 5104 and needle guard 5102 such that the tip of insertion element 5174 is encapsulated by needle guard 5102 when the predetermined spacing is maintained. **FIG. 51A** illustrates a pre-activation position that may be returned to after activation, under a returning force provided by spring 5106, compressed during deployment of insertion element 5174. In some embodiments, the spring can be integrated into needle hub 5104 or needle guard 5102.

[0305] **FIG. 51B** illustrates needle hub 5104, insertion element 5174, needle guard 5102, spring 5174, and base 5130 of the applicator in the distal, deployed position. As shown, insertion element 5174 has been driven through needle guard 5102 and through an opening in base 5130. Since needle hub 5104 is fixed to insertion element 5174, deployment of insertion element 5174 to the distal, deployed position closes the distance between needle hub 5104 and needle guard 5102, thereby compressing spring 5106 (not shown in **FIG. 51B**). The energy stored in compressing spring 5106 is then utilized to force needle guard 5102 substantially to its pre-activation position, thereby encapsulating the tip of insertion element 5174. It is contemplated that the features described in **FIGs. 51A-51B** provide protection from needle stick hazards.

[0306] **FIGs. 52A-52B** illustrate a cross-sectional view and a top plan view, respectively, of an infusion cannula 5264 integrated into on-skin sensor assembly 160 of an analyte sensor system, according to some embodiments. In **FIG. 52A**, on-skin sensor assembly 160 is illustrated as including sensor 138 and a fill port 5262 configured to receive a fluid, gel, or medication (e.g., insulin) and cannula 5264 configured to deliver the fluid or gel through skin 130 of the host. In some embodiments, fill port 5262 comprises a septum material that maintains a seal for the transcutaneous cannula and is capable of being pierced (e.g. by a hypodermic needle attached to a syringe) and allow for dosing the medication. This septum may be configured to self-seal after removal of the needle from the skin of the host. The infusion cannula and analyte sensor may be inserted transcutaneously by the same applicator device. It is envisioned that a sharp (e.g. needle) placed within the lumen of an infusion cannula and placed in parallel with the insertion element (e.g. attached to needle carrier assembly such as 508) for analyte sensors may be added to the analyte applicators (e.g. applicator 500, 800, 900, 1000,

etc.). In **FIG. 52B**, on-skin sensor assembly 160 is illustrated as including an adhesive patch 5264 configured to adhere on-skin sensor assembly 160 to skin 130 of the host.

Sensor Retention Embodiments

[0307] In some embodiments, an insertion element, such as an open-sided needle may be utilized to insert at least a portion of a sensor wire into the skin of a host. However, such embodiments generally operate best when the sensor wire remains seated in a channel of the open-sided needle before and during insertion. In addition, if the open-sided needle does not retain the sensor in the channel of the needle, the sensor may fail to deploy into the tissue. Accordingly, **FIGs. 53-59** illustrate several embodiments of applicators that include sensor retention features configured to retain the sensor wire within a channel of the insertion element at least before activation of the applicator. Although particular applicators are shown, these retention features may be incorporated into any applicator described by this disclosure.

[0308] **FIG. 53** illustrates a cross-sectional view of a sensor retention mechanism for an applicator 5300 for an analyte sensor system, according to some embodiments. Applicator 5300 includes an applicator housing 5302 having a retaining feature 5384, for example a hook or protrusion. Applicator 5300 further includes on-skin sensor assembly 160 having sensor 138, and an insertion element 5374 configured to guide sensor 138. Applicator 5300 further comprises a retention element 5382, which may comprise an elastomeric band (e.g., a rubber band), a flexible plastic, or metallic wire configured to press against an open side of insertion element 5374 thereby retaining sensor 138 in insertion element 5374. Upon activation of applicator 5300, an orientation or position of one or more of retaining feature 5384, retention element 5382 or insertion element 5374 may be altered such that sensor 138 is no longer actively retained within insertion element 5374. For example, insertion element 5374 may be configured to progress in the proximal direction at the beginning of activation. The insertion element 5374 is withdrawn from the retention element allowing the retention element to recoil and clear the pathway of insertion for the on-skin assembly.

[0309] **FIG. 54** illustrates a perspective view of another sensor retention mechanism 5482 for an applicator 5400 for an analyte sensor system, according to some embodiments. In **FIG. 54**, sensor retention mechanism 5482 comprises a flexible or substantially rigid insert configured to rest against applicator housing 5402 and against insertion element 5474, thereby

retaining sensor 138 in insertion element 5474. For example, retention mechanism 5482 may comprise a paper, plastic, elastomeric, metallic or polymeric sheet configured for removal before activation of applicator 5400. In some embodiments, retention mechanism 5482 may be manufactured or cut to include a tab 5486 configured to press against insertion element 5474, thereby retaining sensor 138 in insertion element 5474.

[0310] In some embodiments, retention mechanism 5482 may be coupled to a liner of an adhesive patch of on-skin sensor assembly 160 such that when the liner is removed, in preparation for application of on-skin sensor assembly 160, retention mechanism 5482 may be simultaneously removed.

[0311] In some other embodiments, tab 5486 may be disposed at such an angle that, rather than holding insertion element 5474 and sensor 138 between tab 5486 and another portion of retention mechanism 5482, insertion element 5474 and sensor 138 are configured to pierce and pass at least partially through tab 5486 such that sensor 138 is retained within a channel of insertion element 5474.

[0312] **FIG. 55** illustrates a cutaway view of another sensor retention element 5592 for an applicator 5500 for an analyte sensor system, according to some embodiments. As shown, retention element 5592 may comprise a pad comprising foam, an elastomer, or any other suitable material, and insertion element 5574 may be inserted at least partially into retention element 5592 such that sensor 138 (not shown in **FIG. 55**) is retained within insertion element 5574. Retention element 5592 may be coupled to a bottom cap 5590 which is removable prior to activation of applicator 5500.

[0313] **FIGs. 56A-56B** illustrate perspective views of another sensor retention element 5682 for an applicator 5600 for an analyte sensor system, according to some embodiments. Sensor retention element 5682 may comprise a paddle or other surface configured to rest against insertion element 5674 in a retaining position, thereby retaining sensor 138 in the insertion element 5674. **FIG. 56A** illustrates sensor retention element 5682 in the retaining position. Sensor retention element 5682 is configured to rotate, slide, or move away from insertion element 5674 into a non-retaining position, thereby putting applicator 5600 in a state for activation. In some embodiments the arm of sensor retention element 5682 is configured to automatically move during or after activation into a non-retaining position via a linkage attached

to an element of the applicator. **FIG. 56B** illustrates sensor retention element 5682 in the non-retaining position.

[0314] In some embodiments, sensor 138 may be retained in a channel of an insertion element by an elastomeric band disposed around at least a portion of insertion element (e.g., an O-ring or any other flexible band material). The elastomeric band may be removed manually before deployment, or alternatively, may be removed from insertion element automatically by some operation of the applicator upon activation. In some embodiments (e.g. applicator 500) the insertion element is configured to move in the proximal direction during the first portion (e.g. by changing the starting position of the scotch-yoke mechanism) of the insertion cycle. In this embodiment the elastomeric element is able to clear the distal tip of the insertion element and recoil to clear the pathway of insertion of the on skin assembly.

[0315] In some other embodiments, sensor 138 may be retained in a channel of an insertion element by a foam, paper, cardboard, plastic, polymeric tab configured to be pierced by insertion element such that the tab is disposed substantially around a tip of insertion element, thereby retaining sensor 138 in the channel of the insertion element. The tab may be removed manually before deployment, or alternatively, may be removed from insertion element automatically by some operation of the applicator upon activation.

[0316] **FIG. 57** illustrates a perspective view of yet another sensor retention element 5782 for an applicator for an analyte sensor system, according to some embodiments. Sensor retention element 5782 includes a needle hub (not shown in **FIG. 57**) configured to guide insertion element 5774 (e.g., a C-needle), which is it turn configured to guide sensor 138. A flexible sleeve comprising a first portion 5706a and a second portion 5706b is disposed over sensor 138 and insertion element 5774, thereby retaining sensor 138 in insertion element 5774. Upon activation, the needle hub is configured to drive insertion element 5774 in the distal direction, thereby splitting the flexible sleeve and separating first portion 5706a and second portion 5706b. Once split, the flexible sleeve may no longer retain sensor 138 in insertion element 5774.

[0317] **FIG. 58** illustrates a perspective view of yet another sensor retention element 5882 for an applicator for an analyte sensor system, according to some embodiments. Sensor retention element 5882 includes a needle hub (not shown in **FIG. 58**) configured to guide insertion element 5874 (e.g., a C-needle), which is it turn configured to guide sensor 138. A

flexible sleeve comprising a first portion 5806a and a second portion 5806b is disposed over sensor 138 within a channel of insertion element 5874, thereby retaining sensor 138 in insertion element 5874. Upon activation, the needle hub is configured to drive insertion element 5874 in the distal direction, thereby splitting the flexible sleeve and separating first portion 5806a and second portion 5806b. Once split, the flexible sleeve may no longer retain sensor 138 in insertion element 5874.

[0318] **FIGs. 59A-59B** illustrate cutaway views of yet another sensor retention element for an applicator for an analyte sensor system, according to some embodiments. **FIG. 59A** illustrates a position of on-skin sensor assembly 160, an insertion element 5974 guiding sensor 138, and a cannula (e.g. a tube such as PTFE, PE, polymer, metallic, etc.) 5962, configured to retain sensor 138 in an open sided insertion element 5974, during and before applicator activation. In **FIG. 59A**, cannula 5962 may be coupled to on-skin sensor assembly 160 or at least configured to be driven to the distal inserted position along with on-skin sensor assembly 160.

[0319] **FIG. 59B** illustrates on-skin sensor assembly 160, sensor assembly 138, and cannula 5962 in the inserted distal position with respect to skin 130 of the host, insertion element 5974 having been retracted to the proximal retracted positon (not shown in **FIG. 59B**). As shown, sensor 138 may be inserted and disposed through cannula 5962, into skin 130 of the host. Cannula 5962 may provide strain relief and a minimum bend radius for sensor 138, thereby reducing the probability of damage to sensor 138 during deployment and operation. A significant portion of the elongated body of the analyte sensor may extend subcutaneously beyond the cannula so as not to interfere with sensor function.

On-Skin Sensor Assembly Features

[0320] **FIG. 68** illustrates a perspective view of an on-skin sensor assembly 6860, which may include a base 6828. An adhesive patch 6826 can couple the base 6828 to the skin 6830 of the host. In some embodiments, the adhesive patch 6826 may comprise an adhesive suitable for skin adhesion, for example a pressure sensitive adhesive (e.g., acrylic, rubber-based, or other suitable type) bonded to a carrier substrate (e.g., spun lace polyester, polyurethane film, or other suitable type) for skin attachment, though any suitable type of adhesive is also contemplated. An on-skin sensor assembly 6860 may comprise an electronics unit 6840 (e.g., a transmitter) which

may further comprise a glucose sensor module 6834 coupled to a glucose sensor 6838 and to base 6828.

[0321] The applicator system can couple adhesive patch 6826 to skin 6830. The glucose sensor module 6834 may be secured to base 6828 (e.g., via retention elements such as snap fits and/or interference features, adhesive, welding, etc.) to ensure glucose sensor 6838 is coupled to base 6828. In alternative embodiments, the sensor module 6834 and base 6828 are preassembled or manufactured as a single component.

[0322] After on-skin assembly 6860 is applied to a user's skin, a user (or an applicator) can couple electronics unit 6840 (e.g., a transmitter) to on-skin sensor assembly 6860 via retention elements such as snap fits and/or interference features. Electronics unit 6840 can measure and/or analyze glucose indicators sensed by glucose sensor 6838. Electronics unit 6840 can transmit information (e.g., measurements, analyte data, glucose data) to a remotely located device (e.g., 110-114 shown in **FIG. 1**).

[0323] On-skin sensor assembly 6860 may be attached to the host with use of an applicator adapted to provide convenient and secure application. Such an applicator may also be used for attaching electronics unit 6840 to base 6840, inserting sensor 6838 through the host's skin, and/or connecting sensor 6838 to electronics unit 6840. Once electronics unit 6840 is engaged with the base and sensor 6838 has been inserted into the skin (and is connected to the electronics unit 6840), the sensor assembly can detach from the applicator.

[0324] **FIG. 69** illustrates a perspective view of electronics unit 6840 coupled to base 6828 via retention elements such as snap fits and/or interference features. In some embodiments, electronics unit 6840 and base 6828 are coupled by adhesive, welding, or other bonding techniques. Adhesive patch 6826, on a distal face of base 6828, is configured to couple sensor assembly 6860 to the skin.

[0325] Reverting to on-skin sensor assembly 160 as previously described in connection with **FIG. 1**, **FIG. 70** illustrates a perspective view of on-skin sensor assembly 6860. On-skin sensor assembly 6860 may be disposable or reusable. **FIG. 70** further illustrates electronics unit 6840 coupled to a base 6828, and adhesive patch 6826 configured to be attached to on-skin assembly 6860, which, when combined, may be held within the applicator. Adhesive patch 6826 may or may not have a non-adhesive liner when held in the applicator.

[0326] Further, with respect to any of on-skin sensor assembly 160, 260, 360 of **FIGs. 1** and **2A-4**, or on-skin sensor assembly 6860 of **FIGs. 68-70**, on-skin sensor assembly 160, 260, 360, 6860 is subjected to stress on portions of sensor 138, 238, 338, 6838 that are bent as the direction of extension of sensor 138, 238, 338, 6838 transitions from substantially horizontal, within on-skin sensor assembly 160, 260, 360, 6860 to substantially vertical, at the interface between on-skin sensor assembly 160, 260, 360, 6860 and skin 130. **FIGs. 58-63** describe several embodiments that minimize the incidence of sensor damage as well as host discomfort at this interface. While the following description may identify portions of on-skin sensor assembly 160 of **FIG. 1**, such description may be equally applicable to on-skin sensor assembly 260, 360, 6860 of **FIGs. 2A-4, and 68-70**.

[0327] **FIG. 60** illustrates a cutaway view of on-skin assembly 160 having at least a portion of sensor 138 potted in a flexible material, according to some embodiments. On-skin sensor assembly 160 is shown as including at least sensor electronics 140, an insertion element 6074, such as a C-needle for example, passing through an opening in on-skin sensor assembly 160, and sensor 138 coupled or couplable to sensor electronics 140 at a first end, and having a portion that is bent along a bend radius such that a portion of sensor 138 beyond the bend is nested within or against insertion element 6074. Sensor 138 is further illustrated as having a flexible material 6002, e.g., an elastomeric material such as silicone, disposed around at least a portion of the bend in sensor 138. Flexible material 6002 may operate as a strain-relief element by limiting the bend radius of the bend to some predetermined minimum radius that substantially reduces or eliminates damage to sensor 138. In some embodiments, flexible material 6002 may extend to the hole through which sensor 138 passes at the on-skin sensor assembly-to-skin interface, which further provides a seal from moisture ingress to on-skin sensor assembly 160. In some embodiments, a dedicated seal comprising a flexible material may be provided at the hole through which sensor 128 passes in addition to or as an alternative to flexible material 6002.

[0328] **FIG. 61** illustrates a cutaway view of on-skin assembly 160 comprising an open cavity configured to allow a larger bend radius in sensor 138, compared to that shown in **FIG. 60**, according to some embodiments. On-skin sensor assembly 160 is shown as including at least sensor electronics 140, an insertion element 6174, such as a C-needle for example, passing through an opening in on-skin sensor assembly 160, and sensor 138 coupled or couplable to sensor electronics 140 at a first end, and having a portion that is bent along a bend radius such

that a portion of sensor 138 beyond the bend is nested within or against insertion element 6174. A bottom of on-skin sensor assembly 160 further includes an open cavity 6102. Open cavity 6102 allows sensor 138 to bend along a larger minimum bending radius than would be possible for an on-skin sensor assembly that does not include open cavity 6102. Sensor 138 is shown in **FIG. 61** as initiating this bend in advance of reaching open cavity 6102, and arcing in an upward direction at the beginning of the bend, further increasing the potential minimum bend radius of sensor 138. Such a larger bend radius reduces stress and strain on sensor 138, thereby reducing the probability of damage to sensor 138.

[0329] Open cavity 6102 may further promote healing of the open wound caused by insertion of sensor 138 by insertion element 6174 by providing access air access that improves drying of the wound site. Although not shown in **FIG. 61**, on-skin sensor assembly 160 may further include a porous, woven, or spun lace material configured to wick away moisture from sweating or any other source, such as blood from the wound. Open cavity 6102 would further provide a location for small amounts of this liquid, e.g., blood, to collect, thereby preventing it from seeping out and being visible to the host. Although not shown in **FIG. 61**, sensor 138 may further include flexible material 6002, e.g., silicone, disposed around at least a portion of the bend in sensor 138 and/or a seal at the hole through which sensor 138 passes, as previously described in connection with **FIG. 60**.

[0330] **FIG. 62** illustrates a cutaway view of on-skin assembly 160 comprising an open cavity configured to allow a larger bend radius in sensor 138, compared to that shown in **FIG. 60**, according to some embodiments. On-skin sensor assembly 160 is shown substantially as previously described in connection with **FIG. 61**, however, sensor 138 is shown as initiating the upward bend upon reaching, rather than in advance of reaching, open cavity 6102. Although not shown in **FIG. 62**, sensor 138 may further include flexible material 6002, e.g., silicone, disposed around at least a portion of the bend in sensor 138 and/or a seal at the hole through which sensor 138 passes, as previously described in connection with **FIG. 60**. Such a larger bend radius reduces stress and strain on sensor 138, thereby reducing the probability of damage to sensor 138.

[0331] **FIG. 63** illustrates a cutaway view of on-skin assembly 160 comprising an open cavity configured to allow a larger bend radius in sensor 138, compared to that shown in **FIG. 60**, according to some embodiments. Such a larger bend radius reduces stress and strain on

sensor 138, thereby reducing the probability of damage to sensor 138. On-skin sensor assembly 160 is shown substantially as previously described in connection with **FIG. 61**, however, sensor 138 is shown as initiating a bend upon reaching, rather than in advance of reaching, open cavity 6102 and this bend is substantially in the downward direction, rather than first in an upward direction. Although not shown in **FIG. 63**, sensor 138 may further include flexible material 6002, e.g., silicone, disposed around at least a portion of the bend in sensor 138 and/or a seal at the hole through which sensor 138 passes, as previously described in connection with **FIG. 60**. It is contemplated that the components and features described above in FIGS. 60-63 can be implemented in other on-skin sensor assemblies described herein, such as on-skin sensor assembly 260 and 360.

[0332] In addition, during pressure fluctuations, such as at high altitude or vacuum during sterilization processes for example, air present within the applicator may exert a deforming force on on-skin sensor assembly 160. Although not shown in any of **FIGs. 60-63**, in some embodiments, on-skin sensor assembly 160 may have at least a portion formed with a reduced thickness and, therefore, reduced strength and rigidity, such that when applicator 460 is exposed to such pressure fluctuations, the portions having the reduced thickness expand in a controlled manner, thereby reducing or eliminating damage that would otherwise occur to on-skin sensor assembly 160 due to undesirable uncontrolled expansion of on-skin sensor assembly 160. Such a feature may be present in the applicator housing of any applicator described herein.

[0333] **FIGs. 64A-64B** illustrate an optional battery connection feature for on-skin sensor assembly 160, 260 in accordance with some embodiments. **FIG. 64A** illustrates a storage mode, pre-activation. On-skin sensor assembly 160 is illustrated as including a battery 6410 configured to power at least sensor electronics (e.g., transmitter/sensor electronics 140, see **FIG. 1**). On-skin sensor assembly 160 further includes an electrical contact 6402, configured to physically and electrically contact battery 6410, an electrically insulating material 6404 (e.g., polyethylene terephthalate (PET), or any other electrically insulative material) disposed between electrical contact 6402, and a flexible material 6406 (e.g., ductile PET, TPSiV® or any other suitable material) coupled to on-skin sensor assembly 160 and to electrically insulating material 6404. In operation, pre-activation, electrically insulating material 6404 prevents electrical contact between electrical contact 6402 and battery 6410, maintaining on-skin sensor assembly 160 in an unpowered storage mode that prevents battery drain before deployment. During

activation, some portion 6408 of applicator may be configured to push down on flexible material 6406, which is physically coupled to electrically insulating material 6404, thereby shifting electrically insulating material 6404 such that electrical contact 6402 comes into electrical contact with battery 6410 and shifting on-skin sensor assembly 160 into a battery connected operational mode, as will be shown in more detail in connection with **FIG. 64B**.

[0334] **FIG. 64B** illustrates the battery connected, operational mode of on-skin sensor assembly 160 discussed in **FIG. 64A**. Portion 6408 of applicator is illustrated as having pushed down or deformed flexible material 6406 and moved electrically insulating material 6404 laterally such that electrical contact 6402 is in electrical contact with battery 6410.

Sterilization, Packaging, and Sealing Embodiments

[0335] For any of the embodiments of applicators expressly described herein, sterilization, packaging, and/or sealing features may also be included. In some embodiments, a user removing the applicator from its packaging and/or its sterilization features may partially or fully energize the applicator (e.g., load unloaded springs). For example, motions such as pulling, twisting, pushing, or tilting required to remove an applicator from its packaging or to remove one or more sterilization and/or sealing features from the applicator may be harnessed to load partially unloaded or fully unloaded springs within the applicator. Such features would provide a benefit in that less energy would have to be stored in the springs of the applicator during its shelf life, prior to its use. Examples of sterilizing, sealing and packaging features contemplated for inclusion with any applicator described herein are described more fully in U.S. Patent Application No. 62/521969, which is incorporated herein by reference it its entirety.

[0336] **FIG. 67** illustrates exemplary sterilization, packaging and sealing features of an applicator configured to apply an on-skin sensor assembly to skin of a host, according to some embodiments. In some embodiments, the applicator (e.g. applicator 500, 800, 900, 1000, etc.). may incorporate features such as sterile barrier, tamper evidence, device sealing and/or device protection. Methods of sterile barrier, tamper evidence, device sealing, and/or device protection are also described in U.S. Patent Application No. 62/521969. Non-limiting examples may include a tamper evident feature 6810 (e.g. **FIGS. 1A – 5B**), a capsule sealing feature 6820 (e.g. **FIGS. 1A-3C**), a gas permeable 6830 and/or non-gas permeable sterile barrier 6840 (e.g. **FIGS.**

1A, 2B, 4B, 5B, 7B, 8B, 9, 11A, 13A, 15A-27B, 29-30B), or device protection feature 6850 (e.g. **FIG. 1A-24B**).

[0337] Tamper evident sealing or other tamper evidence features 6810 allow a consumer to identify when an applicator has been previously used or containment has been breached and, thus, avoid using an applicator that may be faulty or pose an increased health risk if used. Non-limiting examples of tamper evident features 6810 also described in U.S. Patent Application No. U.S. Patent Application No. 62/521969, include ring, peelable layer, perforated tab, adhesive mounted tab, and/or twist-off collar. These features may be incorporated in current embodiments within an applicator housing (e.g. 502) or additional bodies added to the applicator assembly (e.g. cap, shell, lid, tab, peelable layer, frangible, ring, etc.).

[0338] Capsule sealing features 6820 create an enclosed volume from multiple components. Non limiting examples of capsule sealing features also described in U.S. Patent Application No. 62/521969, include one or more removable caps on the top (e.g., proximal) or bottom (e.g., distal) ends of the applicator, through one or more trigger mechanisms comprising integrated caps, through one or more sealing layers that cover one or more orifices, apertures or vents of the applicator, through sterilizable gas-permeable polymers, through sterilizable gas-permeable trigger mechanisms, through protective cups, or any combinations of the same, described in more detail with at least some of **FIGs. 1A-33**. These features may be incorporated in current embodiments within an applicator housing (e.g. 502) or additional bodies added to the applicator assembly (e.g. cap, shell, lid, tab, peelable layer, elastomer, O-ring, adhesive, button, etc.).

[0339] Gas permeable sterile barriers 6830 allow a device to create an enclosed volume that is permeable to a gas (e.g. a sterilization gas) and maintain a microbial barrier to an exterior volume. A non-gas permeable sterile barrier 6840 performs the same functions of a gas permeable sterile barrier with the additional function of blocking gasses than may have deleterious effects (e.g. water vapor). Gas permeable 6830 and/or non-gas permeable sterile barrier 6840 may be used in conjunction or independently as also described in U.S. Patent Application No. 62/521969. These features may be incorporated in current embodiments within an applicator housing (e.g. 502) or additional bodies added to the applicator assembly (e.g. cap, shell, lid, tab, peelable layer, packaging, seal, button, etc.).

[0340] Device protection features 6850 may be adapted to protect functional components of applicators (e.g. applicator 500, 800, 900, 1000, etc.). Functions may include inadvertent activation prevention, drop protection, needle damage protection, or other functions also disclosed in U.S. Patent Application No. 62/521969. These features may be incorporated in current embodiments within an applicator housing (e.g. 502) or additional bodies added to the applicator assembly (e.g. cap, shell, lid, tab, peelable layer, frangible, packaging, seal, button, etc.).

Methods of Applying an On-Skin Sensor Assembly to Skin of a Host

[0341] **FIG. 65** illustrates a flowchart 6500 of a method for applying an on-skin sensor assembly to skin of a host, according to some embodiments. Steps in flowchart 6500 may be performed utilizing any applicator as previously described in connection with any of the previous **FIGs.** Although certain steps are set forth below, a method of using such an applicator may comprise more, fewer, or different steps, in the same or different order from that set forth below.

[0342] Flowchart 6500 illustrates block 6502, including providing an applicator comprising an applicator housing, a needle carrier assembly comprising an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host, a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly, a drive assembly, and an activation element. In some embodiments, the distal direction and the proximal direction extend along an insertion axis of the insertion element.

[0343] Flowchart 6500 further illustrates block 6504, including activating an activation element, wherein activating the activation element causes the drive assembly to drive the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position, thereby inserting the sensor of the on-skin sensor assembly at least partially into the skin of the host.

[0344] **FIG. 66** illustrates exemplary mechanisms for several features of an applicator configured to apply an on-skin sensor assembly to skin of a host, according to some embodiments. The mechanisms described in connection with **FIG. 66** are exemplary and not limiting.

[0345] For example, the feature activation element 6610 as used herein may be considered to include any type of mechanism that, when operated as intended, serves to activate a drive mechanism of an applicator and, thereby, apply an on-skin sensor assembly to skin of a host. For example, an activation element may include an element configured to trigger when pushed, pulled, switched, toggled, slid, triggered, deflected, rotated, deformed or flexed from a first position or state to at least a second position or state. General examples include but are not limited to buttons, slides, hooks, switches, a flexible portion of the applicator housing itself, tabs, or strings. Moreover, although certain embodiments of applicators are described herein as having an activation element in a particular location, any applicator described herein is also contemplated having one or more activation members in any other position, e.g., a top, upper side, medial side, lower side, or bottom of the applicator. Moreover, in some embodiments, two or more activation elements may be operated in tandem in order to activate the applicator. The above-described activation elements may be applied or utilized in connection with any applicator described herein.

[0346] The feature insertion element 6620 as used herein may be considered to include any type of mechanism that, when operated as intended, serves to insert a sensor or sensor wire at least partially into a skin of a host. For example, an insertion element may include, but is not limited to, a regular, circumferential needle, an open sided-needle (e.g., **FIGs. 48A-48B**), a needle with a deflected tip (e.g., **FIG. 49**), a curved, bent or kinked needle (e.g., **FIGs. 47 and 50**), a polymer-coated needle, a hypodermic needle, or the sensor or sensor wire tip itself.

[0347] The feature retention element or on-skin sensor assembly retention element 6630 as used herein may be considered to include any type of mechanism that, when operated as intended, serves to retain an on-skin sensor assembly in a particular position, orientation or constrain the feature to a particular path of motion. For example, a retention element may include, but is not limited to, a hook, a claw, a tab, an arm, an undercut and snap feature, a press fit feature, a deformable and/or elastomeric element (as described in connection with any of **FIGs. 5-7D, 12-14E, 25-27E, 32A-37C** and **41A-46**), or any on-skin sensor assembly retention element illustrated in U.S. Patent Application No. 15/387088 as described above.

[0348] The feature spring and/or energy source 6650 as used herein may be considered to include any suitable type of spring configured to store potential energy when loaded and configured to release at least a portion of that stored potential energy to drive one or more

portions of an applicator as required or desired. For example, a spring may include, but is not limited to, a compression spring, which is configured to store energy when compressed to less than its resting length (e.g., **FIG. 32**), an extension spring, which is configured to store energy when stretched to greater than its resting length (e.g., **FIG. 21**), a single or double torsion spring (e.g., **FIG. 12**), clock spring or power spring, which are configured to store energy in torsional deformation of a portion of the spring from its resting profile, or a leaf spring (e.g., **FIGs. 22** and **25**), which is configured to store energy in the physical deformation of the spring from its resting profile.

[0349] Insertion and/or retraction mechanisms 6660 may be considered to include any suitable mechanism for causing a movement of an insertion element in a distal direction to a distal inserted position, and/or in a proximal direction to a proximal retracted positon. For example, such mechanisms may include, but are not limited to, a scotch yoke mechanism (e.g., **FIG. 5**) a barrel cam (e.g., **FIG. 29**), opposing springs mechanism, a reverse toggling mechanism comprising a lever having a first end, a second end, and a fulcrum at a point between the first and second ends (e.g., **FIG. 31**), a flexible linkage (e.g., **FIGs.18-23**), a spring linkage (e.g. **FIG. 12-14E**), or any hinging or pivoting (e.g. **FIG 25-28H**) apparatus that operates as described in this disclosure.

[0350] Energy storage 6640, for example, as potential energy stored in a spring, for any applicator described in this disclosure may be pre-loaded (e.g., in the factory or before provision to a user), mechanism loaded (e.g., some operation of the applicator loads the spring), or user loaded (e.g., the user provides energy in some form of motion that is utilized to store potential energy in a spring).

[0351] Sensor retention 6670 for any applicator described in this disclosure may be user-removable (e.g., **FIGs. 54, 57, 58**), mechanism-removable (e.g., **FIGs. 53, 56A-56B, 57** and **58**), ex-vivo support feature (e.g., **FIGs. 55-58**), or in-vivo support feature (e.g., **FIGs. 59A-59B**). For example, an elastomeric element such as a rubber band (see **FIG. 53**), a foam, rubber or other pad (see **FIG. 55**), a frangible element (see **FIGs. 57-58**), an adhesive layer, or a wire.

[0352] Elements within each feature category (e.g., 6610, 6620, 6630, 6640, 6650, 6660, 6670) are interchangeable for any applicator described herein. For instance, applicator 500 shown in **FIGS. 5-6H** includes a push button and deflecting arm activation element 504, an open-sided needle insertion element 674, an undercut/snap feature 678a, 678b for on-skin sensor

assembly 160 retention, a pre-loaded energy storage in which the energy source is a single torsion spring 512, and a scotch yoke insertion/retraction mechanism 510. However, in an alternative embodiment, applicator 500 may instead include a switch/toggle activation element, a curved/bent needle insertion element (e.g., 5074), a press fit on-skin sensor assembly retention, and an ex-vivo support feature sensor retention (e.g., **FIGs. 55-58**).

[0353] In another example, applicator 2500 shown in **FIGs. 25-28H** includes a push button and deflecting arm activation element 2504, an open-sided needle insertion element 2674, an undercut/snap feature (e.g., similar to 678a, 678b) on needle carrier assembly 2508 for on-skin sensor assembly 160 retention, a pre-loaded energy storage in which the energy source is a compression spring 2512 and leaf springs 2528, and a hinging or pivoting apparatus 2508, 2524. However, in an alternative embodiment, applicator 2500 may instead include a switch/toggle activation element, a curved/bent needle insertion element (e.g., 5074), a press fit on-skin sensor assembly retention, and an ex-vivo support feature sensor retention (e.g., **FIGs. 55-58**).

[0354] The specification and figures of U.S. Provisional Application No. 62/521969 are provided as an appendix to this application, and include the text and figures of U.S. Patent App. No. 15/387,088 as filed. These documents are designated as "APPENDIX TO DEXCOM.394PR (788.C5.001 DEXCOM 683)", and form a part of this application.

[0355] It should be appreciated that all methods and processes disclosed herein may be used in any glucose monitoring system, continuous or intermittent. It should further be appreciated that the implementation and/or execution of all methods and processes may be performed by any suitable devices or systems, whether local or remote. Further, any combination of devices or systems may be used to implement the present methods and processes.

[0356] Methods and devices that are suitable for use in conjunction with aspects of the preferred embodiments are disclosed in U.S. Pat. No. 4,757,022; U.S. Pat. No. 4,994,167; U.S. Pat. No. 6,001,067; U.S. Pat. No. 6,558,321; U.S. Pat. No. 6,702,857; U.S. Pat. No. 6,741,877; U.S. Pat. No. 6,862,465; U.S. Pat. No. 6,931,327; U.S. Pat. No. 7,074,307; U.S. Pat. No. 7,081,195; U.S. Pat. No. 7,108,778; U.S. Pat. No. 7,110,803; U.S. Pat. No. 7,134,999; U.S. Pat. No. 7,136,689; U.S. Pat. No. 7,192,450; U.S. Pat. No. 7,226,978; U.S. Pat. No. 7,276,029; U.S. Pat. No. 7,310,544; U.S. Pat. No. 7,364,592; U.S. Pat. No. 7,366,556; U.S. Pat. No. 7,379,765; U.S. Pat. No. 7,424,318; U.S. Pat. No. 7,460,898; U.S. Pat. No. 7,467,003; U.S. Pat. No. 7,471,972; U.S. Pat. No. 7,494,465; U.S. Pat. No. 7,497,827; U.S. Pat. No. 7,519,408; U.S. Pat.

No. 7,583,990; U.S. Pat. No. 7,591,801; U.S. Pat. No. 7,599,726; U.S. Pat. No. 7,613,491; U.S. Pat. No. 7,615,007; U.S. Pat. No. 7,632,228; U.S. Pat. No. 7,637,868; U.S. Pat. No. 7,640,048; U.S. Pat. No. 7,651,596; U.S. Pat. No. 7,654,956; U.S. Pat. No. 7,657,297; U.S. Pat. No. 7,711,402; U.S. Pat. No. 7,713,574; U.S. Pat. No. 7,715,893; U.S. Pat. No. 7,761,130; U.S. Pat. No. 7,771,352; U.S. Pat. No. 7,774,145; U.S. Pat. No. 7,775,975; U.S. Pat. No. 7,778,680; U.S. Pat. No. 7,783,333; U.S. Pat. No. 7,792,562; U.S. Pat. No. 7,797,028; U.S. Pat. No. 7,826,981; U.S. Pat. No. 7,828,728; U.S. Pat. No. 7,831,287; U.S. Pat. No. 7,835,777; U.S. Pat. No. 7,857,760; U.S. Pat. No. 7,860,545; U.S. Pat. No. 7,875,293; U.S. Pat. No. 7,881,763; U.S. Pat. No. 7,885,697; U.S. Pat. No. 7,896,809; U.S. Pat. No. 7,899,511; U.S. Pat. No. 7,901,354; U.S. Pat. No. 7,905,833; U.S. Pat. No. 7,914,450; U.S. Pat. No. 7,917,186; U.S. Pat. No. 7,920,906; U.S. Pat. No. 7,925,321; U.S. Pat. No. 7,927,274; U.S. Pat. No. 7,933,639; U.S. Pat. No. 7,935,057; U.S. Pat. No. 7,946,984; U.S. Pat. No. 7,949,381; U.S. Pat. No. 7,955,261; U.S. Pat. No. 7,959,569; U.S. Pat. No. 7,970,448; U.S. Pat. No. 7,974,672; U.S. Pat. No. 7,976,492; U.S. Pat. No. 7,979,104; U.S. Pat. No. 7,986,986; U.S. Pat. No. 7,998,071; U.S. Pat. No. 8,000,901; U.S. Pat. No. 8,005,524; U.S. Pat. No. 8,005,525; U.S. Pat. No. 8,010,174; U.S. Pat. No. 8,027,708; U.S. Pat. No. 8,050,731; U.S. Pat. No. 8,052,601; U.S. Pat. No. 8,053,018; U.S. Pat. No. 8,060,173; U.S. Pat. No. 8,060,174; U.S. Pat. No. 8,064,977; U.S. Pat. No. 8,073,519; U.S. Pat. No. 8,073,520; U.S. Pat. No. 8,118,877; U.S. Pat. No. 8,128,562; U.S. Pat. No. 8,133,178; U.S. Pat. No. 8,150,488; U.S. Pat. No. 8,155,723; U.S. Pat. No. 8,160,669; U.S. Pat. No. 8,160,671; U.S. Pat. No. 8,167,801; U.S. Pat. No. 8,170,803; U.S. Pat. No. 8,195,265; U.S. Pat. No. 8,206,297; U.S. Pat. No. 8,216,139; U.S. Pat. No. 8,229,534; U.S. Pat. No. 8,229,535; U.S. Pat. No. 8,229,536; U.S. Pat. No. 8,231,531; U.S. Pat. No. 8,233,958; U.S. Pat. No. 8,233,959; U.S. Pat. No. 8,249,684; U.S. Pat. No. 8,251,906; U.S. Pat. No. 8,255,030; U.S. Pat. No. 8,255,032; U.S. Pat. No. 8,255,033; U.S. Pat. No. 8,257,259; U.S. Pat. No. 8,260,393; U.S. Pat. No. 8,265,725; U.S. Pat. No. 8,275,437; U.S. Pat. No. 8,275,438; U.S. Pat. No. 8,277,713; U.S. Pat. No. 8,280,475; U.S. Pat. No. 8,282,549; U.S. Pat. No. 8,282,550; U.S. Pat. No. 8,285,354; U.S. Pat. No. 8,287,453; U.S. Pat. No. 8,290,559; U.S. Pat. No. 8,290,560; U.S. Pat. No. 8,290,561; U.S. Pat. No. 8,290,562; U.S. Pat. No. 8,292,810; U.S. Pat. No. 8,298,142; U.S. Pat. No. 8,311,749; U.S. Pat. No. 8,313,434; U.S. Pat. No. 8,321,149; U.S. Pat. No. 8,332,008; U.S. Pat. No. 8,346,338; U.S. Pat. No. 8,364,229; U.S. Pat. No. 8,369,919; U.S. Pat. No. 8,374,667;

U.S. Pat. No. 8,386,004; U.S. Pat. No. 8,394,021; U.S. Pat. No. 8,527,025; U.S. Pat. No. 7,896,809; U.S. Pat. No. 9,119,528; and U.S. Pat. No. 9,119,529.

[0357] Methods and devices that are suitable for use in conjunction with aspects of the preferred embodiments are disclosed in U.S. Patent Publication No. 1203-0032874-A1; U.S. Patent Publication No. 1205-0033132-A1; U.S. Patent Publication No. 1205-0051427-A1; U.S. Patent Publication No. 1205-0090607-A1; U.S. Patent Publication No. 1205-0176136-A1; U.S. Patent Publication No. 1205-0245799-A1; U.S. Patent Publication No. 1206-0015020-A1; U.S. Patent Publication No. 1206-0016700-A1; U.S. Patent Publication No. 1206-0020188-A1; U.S. Patent Publication No. 1206-0020190-A1; U.S. Patent Publication No. 1206-0020191-A1; U.S. Patent Publication No. 1206-0020192-A1; U.S. Patent Publication No. 1206-0036140-A1; U.S. Patent Publication No. 1206-0036143-A1; U.S. Patent Publication No. 1206-0040402-A1; U.S. Patent Publication No. 1206-0068208-A1; U.S. Patent Publication No. 1206-0142651-A1; U.S. Patent Publication No. 1206-0155180-A1; U.S. Patent Publication No. 1206-0198864-A1; U.S. Patent Publication No. 1206-0200020-A1; U.S. Patent Publication No. 1206-0200022-A1; U.S. Patent Publication No. 1206-0200970-A1; U.S. Patent Publication No. 1206-0204536-A1; U.S. Patent Publication No. 1206-0224108-A1; U.S. Patent Publication No. 1206-0235285-A1; U.S. Patent Publication No. 1206-0249381-A1; U.S. Patent Publication No. 1206-0252027-A1; U.S. Patent Publication No. 1206-0253012-A1; U.S. Patent Publication No. 1206-0257995-A1; U.S. Patent Publication No. 1206-0258761-A1; U.S. Patent Publication No. 1206-0263763-A1; U.S. Patent Publication No. 1206-0270922-A1; U.S. Patent Publication No. 1206-0270923-A1; U.S. Patent Publication No. 1207-0027370-A1; U.S. Patent Publication No. 1207-0032706-A1; U.S. Patent Publication No. 1207-0032718-A1; U.S. Patent Publication No. 1207-0045902-A1; U.S. Patent Publication No. 1207-0059196Patent Publication No. 1207-0066873-A1; U.S. Patent Publication No. 1207-0173709-A1; U.S. Patent Publication No. 1207-0173710-A1; U.S. Patent Publication No. 1207-0208245-A1; U.S. Patent Publication No. 1207-0208246-A1; U.S. Patent Publication No. 1207-0232879-A1; U.S. Patent Publication No. 1208-0045824-A1; U.S. Patent Publication No. 1208-0083617-A1; U.S. Patent Publication No. 1208-0086044-A1; U.S. Patent Publication No. 1208-0108942-A1; U.S. Patent Publication No. 1208-0119703-A1; U.S. Patent Publication No. 1208-0119704-A1; U.S. Patent Publication No. 1208-0119706-A1; U.S. Patent Publication No. 1208-0183061-A1; U.S. Patent Publication No. 1208-0183399-A1; U.S. Patent Publication No. 1208-0188731-A1; U.S. Patent Publication No. 1208-0189051-A1; U.S. Patent

Publication No. 1208-0194938-A1; U.S. Patent Publication No. 1208-0197024-A1; U.S. Patent Publication No. 1208-0200788-A1; U.S. Patent Publication No. 1208-0200789-A1; U.S. Patent Publication No. 1208-0200791-A1; U.S. Patent Publication No. 1208-0214915-A1; U.S. Patent Publication No. 1208-0228054-A1; U.S. Patent Publication No. 1208-0242961-A1; U.S. Patent Publication No. 1208-0262469-A1; U.S. Patent Publication No. 1208-0275313-A1; U.S. Patent Publication No. 1208-0287765-A1; U.S. Patent Publication No. 1208-0306368-A1; U.S. Patent Publication No. 1208-0306434-A1; U.S. Patent Publication No. 1208-0306435-A1; U.S. Patent Publication No. 1208-0306444-A1; U.S. Patent Publication No. 1209-0018424-A1; U.S. Patent Publication No. 1209-0030294-A1; U.S. Patent Publication No. 1209-0036758-A1; U.S. Patent Publication No. 1209-0036763-A1; U.S. Patent Publication No. 1209-0043181-A1; U.S. Patent Publication No. 1209-0043182-A1; U.S. Patent Publication No. 1209-0043525-A1; U.S. Patent Publication No. 1209-0045055-A1; U.S. Patent Publication No. 1209-0062633-A1; U.S. Patent Publication No. 1209-0062635-A1; U.S. Patent Publication No. 1209-0076360-A1; U.S. Patent Publication No. 1209-0099436-A1; U.S. Patent Publication No. 1209-0124877-A1; U.S. Patent Publication No. 1209-0124879-A1; U.S. Patent Publication No. 1209-0124964-A1; U.S. Patent Publication No. 1209-0131769-A1; U.S. Patent Publication No. 1209-0131777-A1; U.S. Patent Publication No. 1209-0137886-A1; U.S. Patent Publication No. 1209-0137887-A1; U.S. Patent Publication No. 1209-0143659-A1; U.S. Patent Publication No. 1209-0143660-A1; U.S. Patent Publication No. 1209-0156919-A1; U.S. Patent Publication No. 1209-0163790-A1; U.S. Patent Publication No. 1209-0178459-A1; U.S. Patent Publication No. 1209-0192366-A1; U.S. Patent Publication No. 1209-0192380-A1; U.S. Patent Publication No. 1209-0192722-A1; U.S. Patent Publication No. 1209-0192724-A1; U.S. Patent Publication No. 1209-0192751-A1; U.S. Patent Publication No. 1209-0203981-A1; U.S. Patent Publication No. 1209-0216103-A1; U.S. Patent Publication No. 1209-0240120-A1; U.S. Patent Publication No. 1209-0240193-A1; U.S. Patent Publication No. 1209-0242399-A1; U.S. Patent Publication No. 1209-0242425-A1; U.S. Patent Publication No. 1209-0247855-A1; U.S. Patent Publication No. 1209-0247856-A1; U.S. Patent Publication No. 1209-0287074-A1; U.S. Patent Publication No. 1209-0299155-A1; U.S. Patent Publication No. 1209-0299156-A1; U.S. Patent Publication No. 1209-0299162-A1; U.S. Patent Publication No. 2010-0010331-A1; U.S. Patent Publication No. 2010-0010332-A1; U.S. Patent Publication No. 2010-0016687-A1; U.S. Patent Publication No. 2010-0016698-A1; U.S. Patent Publication No. 2010-0030484-A1; U.S. Patent Publication No. 2010-0036215-A1; U.S. Patent

Publication No. 2010-0036225-A1; U.S. Patent Publication No. 2010-0041971-A1; U.S. Patent Publication No. 2010-0045465-A1; U.S. Patent Publication No. 2010-0049024-A1; U.S. Patent Publication No. 2010-0076283-A1; U.S. Patent Publication No. 2010-0081908-A1; U.S. Patent Publication No. 2010-0081910-A1; U.S. Patent Publication No. 2010-0087724-A1; U.S. Patent Publication No. 2010-0096259-A1; U.S. Patent Publication No. 2010-0121169-A1; U.S. Patent Publication No. 2010-0161269-A1; U.S. Patent Publication No. 2010-0168540-A1; U.S. Patent Publication No. 2010-0168541-A1; U.S. Patent Publication No. 2010-0168542-A1; U.S. Patent Publication No. 2010-0168543-A1; U.S. Patent Publication No. 2010-0168544-A1; U.S. Patent Publication No. 2010-0168545-A1; U.S. Patent Publication No. 2010-0168546-A1; U.S. Patent Publication No. 2010-0168657-A1; U.S. Patent Publication No. 2010-0174157-A1; U.S. Patent Publication No. 2010-0174158-A1; U.S. Patent Publication No. 2010-0174163-A1; U.S. Patent Publication No. 2010-0174164-A1; U.S. Patent Publication No. 2010-0174165-A1; U.S. Patent Publication No. 2010-0174166-A1; U.S. Patent Publication No. 2010-0174167-A1; U.S. Patent Publication No. 2010-0179401-A1; U.S. Patent Publication No. 2010-0179402-A1; U.S. Patent Publication No. 2010-0179404-A1; U.S. Patent Publication No. 2010-0179408-A1; U.S. Patent Publication No. 2010-0179409-A1; U.S. Patent Publication No. 2010-0185065-A1; U.S. Patent Publication No. 2010-0185069-A1; U.S. Patent Publication No. 2010-0185070-A1; U.S. Patent Publication No. 2010-0185071-A1; U.S. Patent Publication No. 2010-0185075-A1; U.S. Patent Publication No. 2010-0191082-A1; U.S. Patent Publication No. 2010-0198035-A1; U.S. Patent Publication No. 2010-0198036-A1; U.S. Patent Publication No. 2010-0212583-A1; U.S. Patent Publication No. 2010-0217557-A1; U.S. Patent Publication No. 2010-0223013-A1; U.S. Patent Publication No. 2010-0223022-A1; U.S. Patent Publication No. 2010-0223023-A1; U.S. Patent Publication No. 2010-0228109-A1; U.S. Patent Publication No. 2010-0228497-A1; U.S. Patent Publication No. 2010-0240975-A1; U.S. Patent Publication No. 2010-0240976 C1; U.S. Patent Publication No. 2010-0261987-A1; U.S. Patent Publication No. 2010-0274107-A1; U.S. Patent Publication No. 2010-0280341-A1; U.S. Patent Publication No. 2010-0286496-A1; U.S. Patent Publication No. 2010-0298684-A1; U.S. Patent Publication No. 2010-0324403-A1; U.S. Patent Publication No. 2010-0331656-A1; U.S. Patent Publication No. 2010-0331657-A1; U.S. Patent Publication No. 2011-0004085-A1; U.S. Patent Publication No. 2011-0009727-A1; U.S. Patent Publication No. 2011-0024043-A1; U.S. Patent Publication No. 2011-0024307-A1; U.S. Patent Publication No. 2011-0027127-A1; U.S. Patent Publication No. 2011-0027453-A1; U.S. Patent

Publication No. 2011-0027458-A1; U.S. Patent Publication No. 2011-0028815-A1; U.S. Patent Publication No. 2011-0028816-A1; U.S. Patent Publication No. 2011-0046467-A1; U.S. Patent Publication No. 2011-0077490-A1; U.S. Patent Publication No. 2011-0118579-A1; U.S. Patent Publication No. 2011-0124992-A1; U.S. Patent Publication No. 2011-0125410-A1; U.S. Patent Publication No. 2011-0130970-A1; U.S. Patent Publication No. 2011-0130971-A1; U.S. Patent Publication No. 2011-0130998-A1; U.S. Patent Publication No. 2011-0144465-A1; U.S. Patent Publication No. 2011-0178378-A1; U.S. Patent Publication No. 2011-0190614-A1; U.S. Patent Publication No. 2011-0201910-A1; U.S. Patent Publication No. 2011-0201911-A1; U.S. Patent Publication No. 2011-0218414-A1; U.S. Patent Publication No. 2011-0231140-A1; U.S. Patent Publication No. 2011-0231141-A1; U.S. Patent Publication No. 2011-0231142-A1; U.S. Patent Publication No. 2011-0253533-A1; U.S. Patent Publication No. 2011-0263958-A1; U.S. Patent Publication No. 2011-0270062-A1; U.S. Patent Publication No. 2011-0270158-A1; U.S. Patent Publication No. 2011-0275919-A1; U.S. Patent Publication No. 2011-0290645-A1; U.S. Patent Publication No. 2011-0313543-A1; U.S. Patent Publication No. 2011-0320130-A1; U.S. Patent Publication No. 2012-0035445-A1; U.S. Patent Publication No. 2012-0040101-A1; U.S. Patent Publication No. 2012-0046534-A1; U.S. Patent Publication No. 2012-0078071-A1; U.S. Patent Publication No. 2012-0108934-A1; U.S. Patent Publication No. 2012-0130214-A1; U.S. Patent Publication No. 2012-0172691-A1; U.S. Patent Publication No. 2012-0179014-A1; U.S. Patent Publication No. 2012-0186581-A1; U.S. Patent Publication No. 2012-0190953-A1; U.S. Patent Publication No. 2012-0191063-A1; U.S. Patent Publication No. 2012-0203467-A1; U.S. Patent Publication No. 2012-0209098-A1; U.S. Patent Publication No. 2012-0215086-A1; U.S. Patent Publication No. 2012-0215087-A1; U.S. Patent Publication No. 2012-0215201-A1; U.S. Patent Publication No. 2012-0215461-A1; U.S. Patent Publication No. 2012-0215462-A1; U.S. Patent Publication No. 2012-0215496-A1; U.S. Patent Publication No. 2012-0220979-A1; U.S. Patent Publication No. 2012-0226121-A1; U.S. Patent Publication No. 2012-0228134-A1; U.S. Patent Publication No. 2012-0238852-A1; U.S. Patent Publication No. 2012-0245448-A1; U.S. Patent Publication No. 2012-0245855-A1; U.S. Patent Publication No. 2012-0255875-A1; U.S. Patent Publication No. 2012-0258748-A1; U.S. Patent Publication No. 2012-0259191-A1; U.S. Patent Publication No. 2012-0260323-A1; U.S. Patent Publication No. 2012-0262298-A1; U.S. Patent Publication No. 2012-0265035-A1; U.S. Patent Publication No. 2012-0265036-A1; U.S. Patent Publication No. 2012-0265037-A1; U.S. Patent Publication No. 2012-0277562-A1; U.S. Patent

Publication No. 2012-0277566-A1; U.S. Patent Publication No. 2012-0283541-A1; U.S. Patent Publication No. 2012-0283543-A1; U.S. Patent Publication No. 2012-0296311-A1; U.S. Patent Publication No. 2012-0302854-A1; U.S. Patent Publication No. 2012-0302855-A1; U.S. Patent Publication No. 2012-0323100-A1; U.S. Patent Publication No. 2013-0012798-A1; U.S. Patent Publication No. 2013-0030273-A1; U.S. Patent Publication No. 2013-0035575-A1; U.S. Patent Publication No. 2013-0035865-A1; U.S. Patent Publication No. 2013-0035871-A1; U.S. Patent Publication No. 1205-0056552-A1; U.S. Patent Publication No. 1205-0182451-A1; U.S. Patent Publication No. 2013-0536650-A1; U.S. Patent Publication No. 2013-0053666-A1; U.S. Patent Publication No. 2010-0331644-A1; U.S. Patent Publication No. 2013-0053665-A1; U.S. Patent Publication No. 2013-0053666-A1; U.S. Patent Publication No. 2013-0060112-A1; U.S. Patent Publication No. 2013-0078912-A1; U.S. Patent Publication No. 2013-0076531-A1; U.S. Patent Publication No. 2013-0076532-A1; U.S. Patent Publication No. 2013-0131478-A1; U.S. Patent Publication No. 2014-0182350-A1; U.S. Patent Publication No. 2014-0188402-A1; U.S. Patent Publication No. 2013-0150692-A1; U.S. Patent Publication No. 2014-0005508-A1; U.S. Patent Publication No. 2014-0094671-A1; U.S. Patent Publication No. 2014-0107450-A1; U.S. Patent Publication No. 2013-0245412-A1; U.S. Patent Publication No. 2014-0088389-A1; U.S. Patent Publication No. 2014-0005505-A1; U.S. Patent Publication No. 2013-0325504-A1; U.S. Patent Publication No. 2013-0321425-A1; and U.S. Patent Publication No. 2014-0129151-A1.

[0358] The above description presents the best mode contemplated for carrying out the present invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use this invention. This invention is, however, susceptible to modifications and alternate constructions from that discussed above that are fully equivalent. Consequently, this invention is not limited to the particular embodiments disclosed. On the contrary, this invention covers all modifications and alternate constructions coming within the spirit and scope of the invention as generally expressed by the following claims, which particularly point out and distinctly claim the subject matter of the invention. While the disclosure has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive.

[0359] All references cited herein are incorporated herein by reference in their entirety. To the extent publications and patents or patent applications incorporated by reference contradict

the disclosure contained in the specification, the specification is intended to supersede and/or take precedence over any such contradictory material.

[0360] Unless otherwise defined, all terms (including technical and scientific terms) are to be given their ordinary and customary meaning to a person of ordinary skill in the art, and are not to be limited to a special or customized meaning unless expressly so defined herein. It should be noted that the use of particular terminology when describing certain features or aspects of the disclosure should not be taken to imply that the terminology is being re-defined herein to be restricted to include any specific characteristics of the features or aspects of the disclosure with which that terminology is associated. Terms and phrases used in this application, and variations thereof, especially in the appended claims, unless otherwise expressly stated, should be construed as open ended as opposed to limiting. As examples of the foregoing, the term 'including' should be read to mean 'including, without limitation,' 'including but not limited to,' or the like; the term 'comprising' as used herein is synonymous with 'including,' 'containing,' or 'characterized by,' and is inclusive or open-ended and does not exclude additional, unrecited elements or method steps; the term 'having' should be interpreted as 'having at least;' the term 'includes' should be interpreted as 'includes but is not limited to;' the term 'example' is used to provide exemplary instances of the item in discussion, not an exhaustive or limiting list thereof; adjectives such as 'known', 'normal', 'standard', and terms of similar meaning should not be construed as limiting the item described to a given time period or to an item available as of a given time, but instead should be read to encompass known, normal, or standard technologies that may be available or known now or at any time in the future; and use of terms like 'preferably,' 'preferred,' 'desired,' or 'desirable,' and words of similar meaning should not be understood as implying that certain features are critical, essential, or even important to the structure or function of the invention, but instead as merely intended to highlight alternative or additional features that may or may not be utilized in a particular embodiment of the invention. Likewise, a group of items linked with the conjunction 'and' should not be read as requiring that each and every one of those items be present in the grouping, but rather should be read as 'and/or' unless expressly stated otherwise. Similarly, a group of items linked with the conjunction 'or' should not be read as requiring mutual exclusivity among that group, but rather should be read as 'and/or' unless expressly stated otherwise.

[0361] Where a range of values is provided, it is understood that the upper and lower limit, and each intervening value between the upper and lower limit of the range is encompassed within the embodiments.

[0362] With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity. The indefinite article 'a' or 'an' does not exclude a plurality. A single processor or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

[0363] It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases 'at least one' and 'one or more' to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles 'a' or 'an' limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases 'one or more' or 'at least one' and indefinite articles such as 'a' or 'an' (e.g., 'a' and/or 'an' should typically be interpreted to mean 'at least one' or 'one or more'); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of 'two recitations,' without other modifiers, typically means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to 'at least one of A, B, and C, etc.' is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., 'a system having at least one of A, B, and C' would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to 'at least

one of A, B, or C, etc.' is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., 'a system having at least one of A, B, or C' would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase 'A or B' will be understood to include the possibilities of 'A' or 'B' or 'A and B.'

[0364] All numbers expressing quantities of ingredients, reaction conditions, and so forth used in the specification are to be understood as being modified in all instances by the term 'about.' Accordingly, unless indicated to the contrary, the numerical parameters set forth herein are approximations that may vary depending upon the desired properties sought to be obtained. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of any claims in any application claiming priority to the present application, each numerical parameter should be construed in light of the number of significant digits and ordinary rounding approaches.

[0365] Furthermore, although the foregoing has been described in some detail by way of illustrations and examples for purposes of clarity and understanding, it is apparent to those skilled in the art that certain changes and modifications may be practiced. Therefore, the description and examples should not be construed as limiting the scope of the invention to the specific embodiments and examples described herein, but rather to also cover all modification and alternatives coming with the true scope and spirit of the invention.

WHAT IS CLAIMED IS:

1. An applicator for applying an on-skin sensor assembly to a skin of a host, the applicator comprising:

an applicator housing;

a needle carrier assembly comprising an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host;

a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly; and

a drive assembly configured to drive the insertion element from a proximal starting position to a distal insertion position, and from the distal insertion position to a proximal retraction position.

2. The applicator of Claim 1, wherein the on-skin sensor assembly comprises an electronics unit.

3. The applicator of Claim 2, wherein the sensor is connected to the electronics unit in the applicator housing.

4. The applicator of Claim 1, wherein the holder is configured to release the on-skin sensor assembly after the sensor is inserted at least partially into the skin of the host.

5. The applicator of Claim 1, further comprising an activation element configured to activate the drive assembly.

6. The applicator of Claim 5, wherein the activation element comprises a deflectable feature.

7. The applicator of Claim 6, wherein the deflectable feature is configured to provide resistance to activation.

8. The applicator of Claim 6, wherein the deflectable feature is configured to return the activation element to a starting positon.

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9. The applicator of Claim 1, wherein the activation element comprises one of a button, a switch, a toggle, a slide, a trigger, and a knob.

10. The applicator of Claims 5, further comprising a safety element configured to prevent operation of the activation element.

11. The applicator of Claim 10, wherein the safety element comprises a tab coupled to the activation element by at least one frangible member.

12. The applicator of Claim 1, wherein the distal direction and the proximal direction extend along an insertion axis of the insertion element.

13. The applicator of Claim 1, wherein the holder comprises an elastomer.

14. The applicator of Claim 1, wherein the holder comprises at least one retention element configured to immobilize the holder to the applicator housing upon the needle carrier assembly reaching the distal insertion position.

15. The applicator of Claim 1, wherein the holder further comprises a retention element configured to:

releasably couple the on-skin sensor assembly to the holder as the needle carrier assembly travels in the distal direction to the distal insertion position; and

decouple the on-skin sensor assembly from the holder as the needle carrier assembly travels in the proximal direction from the distal insertion position.

16. The applicator of Claim 1, wherein the holder comprises a retention element comprising a first end and a second end, wherein:

the first end is immobilized in a guide of the needle carrier assembly thereby releasably coupling the second end to the on-skin sensor assembly as the needle carrier assembly travels in the distal direction to the distal insertion position; and

the first end is unseated from the guide of the needle carrier assembly thereby decoupling the second end from the on-skin sensor assembly as the needle carrier

assembly travels in the proximal direction from the distal insertion position and separates from the holder.

17. The applicator of Claim 1, wherein:

the needle carrier assembly comprises a retention element releasably coupling the on-skin sensor assembly to the holder as the needle carrier assembly travels in the distal direction to the distal insertion position; and

the retention element is configured to deform sufficiently to decouple from the on-skin sensor assembly as the needle carrier assembly travels in the proximal direction from the distal insertion position and separates from the holder.

18. The applicator of Claim 1, wherein:

the holder comprises a deformable retention element releasably coupling the on-skin sensor assembly to the holder, the needle carrier assembly in contact with the deformable retention element thereby preventing the deformable retention element from deforming as the needle carrier assembly travels in the distal direction to the distal insertion position; and

the needle carrier assembly separates from the holder as the needle carrier assembly travels in the proximal direction from the distal insertion position thereby allowing the retention element to deform sufficiently to decouple from the on-skin sensor assembly.

19. The applicator of Claim 1, wherein the needle carrier assembly comprises:

a first retention element configured to releasably couple the holder to the needle carrier assembly; and

a second retention element configured to releasably couple the on-skin sensor assembly to one of the holder and the needle carrier assembly.

20. The applicator of Claim 1, wherein the insertion element comprises a C-needle having flared edges.

21. The applicator of Claim 1, wherein the insertion element comprises a deflected-tip needle.

22. The applicator of Claim 1, wherein the insertion element comprises a needle having a curvilinear profile configured to substantially track a path of insertion of the needle.

23. The applicator of Claim 1, wherein the insertion element comprises a needle and the needle carrier assembly further comprises:

a needle hub configured as a pass through for the needle during insertion of the sensor and further configured to enclose a tip of the needle after insertion of the sensor;

a needle spring configured to drive the needle hub to the tip of the needle after insertion of the sensor.

24. The applicator of Claim 1, wherein the on-skin sensor assembly comprises a fill port configured to receive a fluid or gel and a cannula configured to deliver the fluid or gel through the skin of the host.

25. The applicator of Claim 1, further comprising an elastomeric sensor retention element coupled to the applicator housing at a first end and coupled to at least one of the insertion element and the sensor, the elastomeric sensor retention element configured to retain the sensor within the insertion element prior to activation of the drive assembly.

26. The applicator of Claim 25, wherein, upon activation, the insertion element is configured to progress in the proximal direction such that the elastomeric sensor retention element decouples from the at least one of the insertion element and the sensor.

27. The applicator of Claim 1, further comprising a sensor retention element comprising a tab configured to retain the sensor within the insertion element prior to activation of the drive assembly.

28. The applicator of Claim 1, further comprising a sensor retention element disposed against at least one of the insertion element and the sensor in a first position and configured to rotate away from the insertion element and the sensor in a second position.

29. The applicator of Claim 1, further comprising a sensor retention sleeve disposed around at least a portion of the insertion element and the sensor,

wherein the needle carrier assembly comprises a tapered needle hub configured to split the sensor retention sleeve during insertion of the sensor.

30. The applicator of Claim 1, wherein the sensor comprises a strain relief feature configured to limit the sensor from bending at a bend radius smaller than a predetermined bend radius.

31. The applicator of Claim 30, wherein the strain relief feature comprises an elastomeric material.

32. The applicator of Claim 1, wherein the on-skin sensor assembly comprises an open cavity configured to receive the sensor and provide an area for the sensor to bend from extending in a substantially horizontal direction to extending in a substantially vertical direction.

33. The applicator of Claim 32, wherein the open cavity is configured to guide bodily fluid released from the host as a result of insertion of the sensor at least partially into the skin of the host.

34. The applicator of Claim 1, wherein the on-skin assembly comprises a wicking material configured to absorb a bodily fluid released from the host as a result of insertion of the sensor at least partially into the skin of the host.

35. The applicator of any of Claims 1-34, wherein:

the applicator housing comprises a guide; and

the drive assembly comprises:

a rotating drive element coupled to the needle carrier assembly and comprising a pin configured to travel in the guide during rotation of the rotating drive element; and

a spring configured to, upon activation of the drive assembly, rotate the rotating drive element in a single rotational direction thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position.

36. The applicator of Claim 35, wherein the rotating drive element is configured to convert rotational motion into linear motion.

37. The applicator of Claim 35, wherein the rotating drive element comprises a wheel cam.

38. The applicator of Claim 35, wherein the pin is radially offset from an axis of rotation of the rotating drive element.

39. The applicator of Claim 38, wherein the pin is positioned approximately 30 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the proximal starting position.

40. The applicator of Claim 38, wherein the pin is positioned approximately 180 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the distal insertion position.

41. The applicator of Claim 38, wherein the pin is positioned approximately 330 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the needle carrier assembly is in the proximal retracted position.

42. The applicator of Claim 35, wherein the pin travels in the guide in a direction perpendicular to a direction of extension of the insertion element.

43. The applicator of Claim 35, wherein the guide comprises a slot.

44. The applicator of Claim 43, wherein the slot is stationary during sensor insertion.

45. The applicator of Claim 43, wherein the slot comprises a horizontal slot.

46. The applicator of Claim 43, wherein the slot comprises a vertical slot configured to receive at least the pin of the rotating drive element when loaded through a bottom of the applicator housing.

47. The applicator of Claim 35, wherein the applicator housing is stationary.

48. The applicator of Claim 35, wherein the rotating drive element further comprises a protrusion in contact with a retention element configured to prevent the rotating drive element from rotating.

49. The applicator of Claim 46, wherein the applicator further comprises an activation element configured to deflect the retention element, thereby allowing the rotating drive element to rotate.

50. The applicator of Claim 35, wherein the rotating drive element further comprises a protrusion configured to decouple the on-skin sensor assembly from the needle carrier assembly.

51. The applicator of Claim 48, wherein the protrusion is configured to apply a force to the on-skin sensor assembly during rotation of the rotating drive element.

52. The applicator of Claim 48, wherein the protrusion of the rotating drive element is configured to pass through a slot in the needle carrier assembly as the rotating drive element rotates.

53. The applicator of any of Claims 1-34, wherein the drive assembly comprises a torsion spring, the torsion spring comprising:

a first end coupled to the applicator housing; and

a second end coupled to the needle carrier assembly, wherein, upon activation of the drive assembly, the first end and the second end unwind in opposite directions, thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position.

54. The applicator of Claim 53, wherein the first end and the second end unwinding in opposite directions drives the torsion spring in an arc.

55. The applicator of Claim 54, wherein the arc extends in a direction perpendicular to the distal direction and the proximal direction.

56. The applicator of Claim 53, further comprising a spool coupled to the torsion spring.

57. The applicator of Claim 56, wherein the torsion spring is wrapped around the spool.

58. The applicator of Claim 53, wherein the second end of the torsion spring is configured to drive the insertion element.

59. The applicator of Claim 53, wherein the torsion spring is a double torsion spring.

60. The applicator of Claim 53, wherein the first end of the torsion spring is coupled to a protrusion of the applicator housing.

61. The applicator of Claim 53, wherein the second end of the torsion spring is coupled to a protrusion of the needle carrier assembly.

62. The applicator of Claim 53, wherein the drive assembly further comprises a linkage element comprising:

a first end coupled to the first end of the torsion spring;

a second end coupled to the second end of the torsion spring; and

a hinge substantially aligned with a winding axis of the torsion spring.

63. The applicator of Claim 62, wherein the linkage element comprises a flex linkage.

64. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a linkage element comprising:

a first end coupled to the applicator housing;

a second end coupled to the needle carrier assembly; and

a hinge disposed between the first end and the second end;

a torsion spring comprising:

a first end coupled to the needle carrier assembly; and

a second end coupled to the linkage element between the second end and the hinge,

wherein, upon activation of the drive assembly, the second end is configured to drive the linkage element such that the insertion element is driven from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retracted position.

65. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a linkage element comprising:

a first end coupled to the applicator housing;

a second end coupled to the needle carrier assembly; and

a hinge disposed between the first end and the second end;

a torsion spring comprising:

a first end coupled to the applicator housing; and

a second end coupled to the linkage element between the first end and the hinge,

wherein, upon activation of the drive assembly, the second end is configured to drive the linkage element such that the insertion element is driven

the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retracted position.

66. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a linkage element comprising:

a first end coupled to the applicator housing;

a second end coupled to the needle carrier assembly; and

a hinge disposed between the first end and the second end;

an extension spring coupled to the linkage element,

wherein, upon activation of the drive assembly, the extension spring is configured to drive the linkage element such that the insertion element is driven in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position.

67. The applicator of any of Claims 1-34, wherein the drive assembly comprises a leaf spring comprising:

a first end coupled to the applicator housing; and

a second end coupled to the needle carrier assembly, wherein, upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element at least in the distal direction to the distal insertion position.

68. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a linkage element comprising:

a first end coupled to the applicator housing;

a second end coupled to the needle carrier assembly; and

a hinge disposed between the first end and the second end;

a leaf spring comprising:

a first end coupled to the needle carrier assembly; and

a second end coupled to the linkage element between the second end and the hinge,

wherein, upon activation of the drive assembly, the leaf spring is configured to decompress, thereby driving the insertion element in the distal direction to the distal insertion position and in the proximal direction from the distal insertion position.

69. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

an insertion spring configured to, upon activation of the drive assembly, drive the insertion element in the distal direction to the distal insertion position; and

a retraction spring in contact with the needle carrier assembly and configured to drive the insertion element from the distal insertion position to the proximal retracted position.

70. The applicator of Claim 69, wherein the insertion spring comprises a compression spring.

71. The applicator of Claim 69, wherein the retraction spring comprises a leaf spring.

72. The applicator of Claim 69, wherein the retraction spring is configured retract the insertion element from the skin of the host.

73. The applicator of Claim 69, wherein, upon activation of the drive assembly, a portion of energy stored in the insertion spring is transferred to the retraction spring as the insertion spring drives the insertion element in the distal direction.

74. The applicator of Claim 69, wherein:

the insertion spring comprises a first end coupled to the applicator housing and a second end coupled to the holder; and

the holder is coupled to the needle carrier assembly while the insertion spring drives the insertion element in the distal direction to the distal insertion position and decoupled from the needle carrier assembly when the retraction spring drives the insertion element in the proximal direction from the distal insertion position.

75. The applicator of Claim 69, wherein the insertion element is configured to travel in an arc when driven in the distal direction and in the proximal direction.

76. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a rotating drive element comprising a ridge configured to slide along a channel in the needle carrier assembly, the ridge defining a variable cam path around at least a portion of a circumference of the rotating drive element; and

a torsion spring configured to, upon activation of the drive assembly, rotate the rotating drive element thereby driving the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position based on the variable cam path.

77. The applicator of Claim 76, wherein the torsion spring is configured to, upon activation of the drive assembly, rotate the rotating drive element in a single direction through an angle of greater than zero degrees and less than 360 degrees.

78. The applicator of Claim 76, wherein the rotating drive element comprises a barrel cam.

79. The applicator of Claim 76, wherein the rotating drive element is configured to rotate in a plane substantially perpendicular to the proximal direction and the distal direction.

80. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a guide member coupled to the applicator housing;

a hub configured to slide along the guide member, the hub in contact with a reverse toggling element through a first portion of travel along the guide member and in contact with the needle carrier assembly through a second portion of travel along the guide member;

the reverse toggling element, comprising:

a fulcrum,

a first end in contact with the hub through the first portion of travel along the guide member, and

a second end coupled with the needle carrier assembly; and

a spring configured to, upon activation of the drive assembly:

drive the hub in a proximal direction through the first portion of travel along the guide member, thereby driving the insertion element in the distal direction to the distal insertion position, and

drive the hub in the proximal direction through the second portion of travel along the guide member, thereby driving the insertion element in the proximal direction from the distal insertion position.

81. The applicator of any of Claims 1-34, wherein the drive assembly comprises:

a first spring configured to, upon activation of the drive assembly, drive the needle carrier assembly in the distal direction to a distal insertion position; and

a second spring configured to drive the needle carrier assembly in the proximal direction from the distal insertion position.

82. The applicator of Claim 81, wherein the first spring and the second spring are precompressed before activation of the drive assembly.

83. The applicator of Claim 81, wherein at least a portion of energy stored in the first spring is transferred to the second spring as the needle carrier assembly is driven in the distal direction to the distal insertion position.

84. A method for applying an on-skin sensor assembly to skin of a host, the method comprising:

providing an applicator comprising:

an applicator housing;

a needle carrier assembly comprising an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host;

a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly;

a drive assembly; and

an activation element; and

activating the activation element, wherein activating the activation element causes the drive assembly to drive the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position to a proximal retraction position, thereby inserting the sensor of the on-skin sensor assembly at least partially into the skin of the host.

85. The method of Claim 84, wherein the distal direction and the proximal direction extend along an insertion axis of the insertion element.

86. The method of Claim 84, wherein:

the applicator housing comprises a guide; and

the drive assembly comprises:

a rotating drive element coupled to the needle carrier assembly and comprising a pin configured to travel in the guide during rotation of the rotating drive element; and

a spring configured to, upon activation of the drive assembly, rotate the rotating drive element in a single rotational direction thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position.

87. The method of Claim 86, wherein the rotating drive element is configured to convert rotational motion into linear motion.

88. The method of Claim 86, wherein the rotating drive element comprises a wheel cam.

89. The method of Claim 86, wherein the pin is radially offset from an axis of rotation of the rotating drive element.

90. The method of Claim 89, wherein the pin is positioned approximately 30 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the proximal starting position.

91. The method of Claim 89, wherein the pin is positioned approximately 180 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the insertion element is in the distal insertion position.

92. The method of Claim 89, wherein the pin is positioned approximately 330 degrees from a bottom center orientation relative to the axis of rotation of the rotating drive element when the needle carrier assembly is in the proximal retracted position.

93. The method of Claim 86, wherein the guide comprises a slot.

94. The method of any of Claims 84-93, wherein the drive assembly comprises a torsion spring, the torsion spring comprising:

a first end coupled to the applicator housing; and

a second end coupled to the needle carrier assembly, wherein, upon activation of the drive assembly, the first end and the second end unwind in opposite directions, thereby driving the insertion element from the proximal starting position to the distal insertion position, and from the distal insertion position to the proximal retraction position.

95. The method of Claim 94, wherein the first end and the second end unwinding in opposite directions drives the torsion spring in an arc.

96. The method of Claim 95, wherein the arc extends in a direction perpendicular to the distal direction and the proximal direction.

97. The method of Claim any of Claims 84-93, wherein the drive assembly comprises:

an insertion spring configured to, upon activation of the drive assembly, drive the insertion element in the distal direction to the distal insertion position; and

a retraction spring in contact with the needle carrier assembly and configured to drive the insertion element from the distal insertion position to the proximal retracted position.

98. The method of Claim 97, wherein the insertion spring comprises a compression spring.

99. The method of Claim 97, wherein the retraction spring comprises a leaf spring.

100. The method of Claim 97, wherein, upon activation of the drive assembly, a portion of energy stored in the insertion spring is transferred to the retraction spring as the insertion spring drives the insertion element in the distal direction.

101. The method of Claim 97, wherein:

the insertion spring comprises a first end coupled to the applicator housing and a second end coupled to the holder; and

the holder is coupled to the needle carrier assembly while the insertion spring drives the insertion element in the distal direction to the distal insertion position and decoupled from the needle carrier assembly when the retraction spring drives the insertion element in the proximal direction from the distal insertion position.

102. The method of Claim 97, wherein the insertion element is configured to travel in an arc when driven in the distal direction and in the proximal direction.

103. The method of Claim any of Claims 84-93, wherein the drive assembly comprises:

a rotating drive element comprising a ridge configured to slide along a channel in the needle carrier assembly, the ridge defining a variable cam path around at least a portion of a circumference of the rotating drive element; and

a torsion spring configured to, upon activation of the drive assembly, rotate the rotating drive element thereby driving the insertion element in a distal direction to a distal insertion position and in a proximal direction from the distal insertion position based on the variable cam path.

104. The method of Claim 103, wherein the torsion spring is configured to, upon activation of the drive assembly, rotate the rotating drive element in a single direction through an angle of greater than zero degrees and less than 360 degrees.

105. The method of Claim 103, wherein the rotating drive element comprises a barrel cam.

106. The method of Claim 103, wherein the rotating drive element is configured to rotate in a plane substantially perpendicular to the proximal direction and the distal direction.

107. The method of Claim any of Claims 84-93, wherein the drive assembly comprises:

a guide member coupled to the applicator housing;

a hub configured to slide along the guide member, the hub in contact with a reverse toggling element through a first portion of travel along the guide member and in contact with the needle carrier assembly through a second portion of travel along the guide member;

the reverse toggling element, comprising:

a fulcrum,

a first end in contact with the hub through the first portion of travel along the guide member, and

a second end coupled with the needle carrier assembly; and

a spring configured to, upon activation of the drive assembly:

drive the hub in a proximal direction through the first portion of travel along the guide member, thereby driving the insertion element in the distal direction to the distal insertion position, and

drive the hub in the proximal direction through the second portion of travel along the guide member, thereby driving the insertion element in the proximal direction from the distal insertion position.

108. The method of Claim any of Claims 84-93, wherein the drive assembly comprises:

a first spring configured to, upon activation of the drive assembly, drive the needle carrier assembly in the distal direction to a distal insertion position; and

a second spring configured to drive the needle carrier assembly in the proximal direction from the distal insertion position.

109. The method of Claim 108, wherein at least a portion of energy stored in the first spring is transferred to the second spring as the needle carrier assembly is driven in the distal direction to the distal insertion position.

TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS

ABSTRACT

The present embodiments relate generally to applicators of on-skin sensor assemblies for measuring an analyte in a host, as well as their method of use and manufacture. In some aspects, an applicator for applying an on-skin sensor assembly to a skin of a host is provided. The applicator includes an applicator housing, a needle carrier assembly comprising an insertion element configured to insert a sensor of the on-skin sensor assembly into the skin of the host, a holder releasably coupled to the needle carrier assembly and configured to guide the on-skin sensor assembly while coupled to the needle carrier assembly, and a drive assembly configured to drive the insertion element from a proximal starting position to a distal insertion position, and from the distal insertion position to a proximal retraction position.

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APPLICATORS FOR APPLYING TRANSCUTANEOUS ANALYTE SENSORS AND ASSOCIATED METHODS OF MANUFACTURE

Field of the Invention

[0001] An applicator for applying an on-skin assembly to skin of a host and methods of their use and/or manufacture are provided. More particularly, apparatuses for applying a transcutaneous analyte assembly to skin of a host for accurately measuring blood glucose of the host and methods of their use and/or manufacture are provided.

Background of the Invention

[0002] Diabetes mellitus is a disorder in which the pancreas cannot create sufficient insulin (Type I or insulin dependent) and/or in which insulin is not effective (Type 2 or non–insulin dependent). In the diabetic state, the victim suffers from high blood sugar, which can cause an array of physiological derangements associated with the deterioration of small blood vessels, for example, kidney failure, skin ulcers, or bleeding into the vitreous of the eye. A hypoglycemic reaction (low blood sugar) can be induced by an inadvertent overdose of insulin, or after a normal dose of insulin or glucose-lowering agent accompanied by extraordinary exercise or insufficient food intake.

[0003] Conventionally, a person with diabetes carries a self-monitoring blood glucose (SMBG) monitor, which typically requires uncomfortable finger pricking methods. Due to the lack of comfort and convenience, a person with diabetes normally only measures his or her glucose levels two to four times per day. Unfortunately, such time intervals are spread so far apart that the person with diabetes likely finds out too late of a hyperglycemic or hypoglycemic condition, sometimes incurring dangerous side effects. Glucose levels may be alternatively monitored continuously by a sensor system including an on-skin sensor assembly. The sensor system may have a wireless transmitter which transmits measurement data to a receiver which can process and display information based on the measurements.

[0004] This Background is provided to introduce a brief context for the Summary and Detailed Description that follow. This Background is not intended to be an aid in determining the scope of the claimed subject matter nor be viewed as limiting the claimed subject matter to implementations that solve any or all of the disadvantages or difficulties presented above.

SUMMARY

[0005] The present apparatuses and methods of manufacture relate to systems and methods for measuring an analyte in a host, systems and methods for manufacturing a transcutaneous analyte measurement system, and systems and methods for applying a transcutaneous analyte measurement system to skin of a host. The various embodiments of the present systems and methods have several features, no single one of which is solely responsible for their desirable attributes. Without limiting the scope of the present embodiments as expressed by the claims that follow, their more prominent features now will be discussed briefly. After considering this discussion, and particularly after reading the section entitled "Detailed Description," one will understand how the features of the present embodiments provide the advantages described herein.

[0006] According to a first aspect, an applicator for applying an on-skin assembly to skin of a host is provided. The applicator includes an insertion assembly configured to insert at least a portion of the sensor assembly into the skin of the host. The applicator includes a housing configured to house the insertion assembly. The housing includes an aperture through which the sensor assembly is configured to pass. The applicator includes an actuation member configured to, upon activation, cause the insertion assembly to insert at least the portion of the sensor assembly into the skin of the host. The applicator includes a sealing element configured to provide a sterile barrier and a vapor barrier between an internal environment of the housing and an external environment of the housing.

[0007] In some embodiments, the sealing element is releasable from the applicator. In some embodiments, the applicator further includes the on-skin assembly. In some embodiments, the on-skin assembly comprises a sensor. In some embodiments, the on-skin assembly comprises a transmitter. In some embodiments the on-skin assembly comprises an adhesive layer configured to adhere the on-skin assembly to the skin of the host. In some embodiments, the applicator further includes a support member configured to inhibit at least lateral movement of the insertion assembly. In some embodiments, the support member comprises an elastomeric membrane. In some embodiments, the insertion assembly comprises a needle. In some embodiments, the applicator further includes one or more ridges or recesses configured to provide a tactile indication of grip for the host. In some embodiments, the applicator has a cross-sectional shape configured to provide a tactile indication of grip for the host. In some

embodiments, the applicator further includes at least one protrusion configured to inhibit rolling of the applicator. In some embodiments, the housing comprises a vent configured to be permeable to a sterilizing gas. In some embodiments, the sealing element is configured to seal the vent. In some embodiments, the sealing element is configured to seal both the aperture and the actuation member. In some embodiments, the actuation member comprises a material that is permeable to a sterilizing gas. In some embodiments, the sealing element comprises at least one of a metallic foil (e.g. aluminum, titanium), a metallic substrate, aluminum oxide coated polymer, parylene, a polymer coated with a metal applied via vapor metallization, silicon dioxide coated polymer, or any material having a moisture vapor transmission rate less than 10 grams/100in^2 or preferably less than 1 grams/100in^2.

[0008] In some embodiments, the sealing element comprises a removable cap configured to couple with a portion of the housing. In some embodiments, the removable cap is configured to couple with a proximal portion of the housing. In some embodiments, the removable cap is configured to couple with a distal portion of the housing. In some embodiments, the removable cap is configured to couple with the housing in a single axial orientation. In some embodiments, the removable cap is configured to couple with the portion of the housing via threads. In some embodiments, the removable cap is configured to couple with the portion of the housing via a frangible member. In some embodiments, the frangible member is configured to provide a tamper indication when broken. In some embodiments, the sealing element further comprises an o-ring configured to provide a seal between the removable cap and the housing. In some embodiments, the removable cap covers the actuation member.

[0009] In some embodiments, the applicator further includes a tamper indicator. In some embodiments, the sealing element comprises a first layer being permeable to a sterilizing gas and a second layer being substantially impermeable to water vapor. In some embodiments, the sealing element comprises a first layer being substantially impermeable to water vapor and sealing the aperture. In some embodiments, the sealing element further comprises a second layer being substantially impermeable to water vapor and sealing the actuation member. In some embodiments, the sealing element comprises a peelable layer coupled to at least a portion of the housing. In some embodiments, the peelable layer is configured to provide a tamper indication when removed. In some embodiments, the peelable layer is configured to seal a distal opening of the housing. In some embodiments, the peelable layer is configured to further seal the actuation

member. In some embodiments, the peelable layer is configured to seal a vent configured to be permeable to a sterilizing gas. In some embodiments, the vent is disposed on a side of the housing. In some embodiments, a porous polymeric component is inserted into the vent.

[0010] In some embodiments, the sealing element comprises a flexible member disposed over at least a portion of the housing. In some embodiments, the flexible member comprises an elastomer. In some embodiments, the flexible member covers the actuation member. In some embodiments, the flexible member is operatively coupled to the actuation member. In some embodiments, the flexible member has a bistable configuration so as to provide a visual indication of deployment after activation. In some embodiments, the sealing element comprises a frangible member. In some embodiments, the frangible member covers the actuation member, and wherein removal of the frangible member exposes the actuation member for activation.

[0011] In some embodiments, the sealing element comprises a cup having a removable lid. In some embodiments, the cup is configured to be collapsible after removal of the lid. In some embodiments, the cup is configured to seal applicator from an environment outside the cup. In some embodiments, the cup comprises an on-skin assembly alignment feature. In some embodiments, the cup comprises a needle protection feature. In some embodiments, the sealing element comprises a plug configured to couple to the housing via a friction fit.

[0012] In some embodiments, the actuation member is disposed on a side of the housing. In some embodiments, the actuation member is disposed on a proximal portion of the housing. In some embodiments, the actuation member is recessed into the proximal portion of the housing. In some embodiments, the actuation member comprises a cap coupled to a proximal portion of the housing. In some embodiments, the actuation member is configured to be activated by moving the cap in a distal direction. In some embodiments, the sealing element further comprises a sealing layer disposed between the cap and the housing. In some embodiments, the cap comprises a protrusion configured to pierce the sealing layer and thereby activate the insertion assembly. In some embodiments, the insertion assembly is driven by a spring force. In some embodiments, the needle is retracted from the insertion assembly after the insertion assembly inserts the on-skin assembly. In some embodiments, the applicator further includes a safety member configured to prevent activation of the actuation member. In some embodiments, the safety member comprises a frangible member, the frangible member being configured to prevent activation of the actuation member, at least until the frangible member is broken.

[0013] In some embodiments, the sealing element comprises a first portion comprising a plurality of perforations and an adhesive layer disposed on a first side of the first portion. In some embodiments, the sealing element further comprises a second portion disposed adjacent to the first side of the first portion, the second portion configurable in a first configuration wherein the first portion is spatially separated from the second portion and a second configuration wherein the second portion is adhered to the first portion via the adhesive layer, wherein the sealing element is permeable to a sterilizing gas in the first configuration, and the sealing element is impermeable to the sterilizing gas in the second configuration. In some embodiments, the second portion is configured to transition from the first configuration to the second configuration when the applicator is subjected to a partial vacuum exceeding a threshold. In some embodiments, the housing is disposable.

[0014] In a second aspect, a method of manufacturing an applicator configured to apply a sensor assembly to skin of a host is provided. The method includes providing an insertion assembly configured to insert at least a portion of the sensor assembly into the skin of the host. The method includes providing a housing configured to house the insertion assembly. The housing comprising an aperture through which the sensor assembly is configured to pass. The method includes providing an actuation member configured to, upon activation, cause the insertion assembly to insert at least the portion of the sensor assembly into the skin of the host. The method includes providing a releasable sealing element configured to provide a sterile barrier and a vapor barrier between an internal environment of the housing and an external environment of the housing.

[0015] In a third aspect, a method of manufacturing an applicator configured to apply a sensor assembly to skin of a host is provided. The method includes providing an insertion assembly configured to insert at least a portion of the sensor assembly into the skin of the host. The method includes providing a housing configured to house the insertion assembly. The housing comprising an aperture through which the sensor assembly is configured to pass. The method includes providing an actuation member configured to, upon activation, cause the insertion assembly to insert at least the portion of the sensor assembly into the skin of the host. The method includes exposing at least an internal environment of the housing to a sterilizing gas. The method includes allowing for egress of the sterilizing gas from the internal environment of

the housing. The method includes sealing the internal environment of the housing from an external environment of the housing.

[0016] In some embodiments, at least sealing the internal environment of the housing from an external environment of the housing is performed simultaneously for a plurality of applicators. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting the plurality of applicators to a partial vacuum exceeding a threshold such that a sealing element of each of the plurality of applicators transitions from being permeable to the sterilizing gas to being impermeable to the sterilizing gas. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting the plurality of applicators to a physical force sufficient to cause a sealing element of each of the plurality of applicators to transition from a first physical configuration permeable to the sterilizing gas to a second physical configuration impermeable to the sterilizing gas. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting a sealing element, comprising a plurality of perforations, of each the plurality of applicators to a temperature sufficient to at least partially melt each of the sealing elements thereby sealing the plurality of perforations in each of the sealing elements. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting a sealing element, comprising a porous polymeric component, of each of the plurality of applicators to a temperature sufficient to form a sintered layer in the porous polymeric component of each sealing element. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises depositing a layer impermeable to the sterilizing gas on at least a portion of each of the plurality of applicators. In some embodiments, the layer comprises at least one of aluminum oxide, parylene, a vapor metallization, silicon dioxide, or a material applied via ion beam sputtering.

[0017] This Summary is provided to introduce a selection of concepts in a simplified form. The concepts are further described in the Detailed Description section. Elements or steps other than those described in this Summary are possible, and no element or step is necessarily required. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended for use as an aid in determining the scope of the

claimed subject matter. The claimed subject matter is not limited to implementations that solve any or all disadvantages noted in any part of this disclosure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] These and other features, aspects, and advantages are described below with reference to the drawings, which are intended to illustrate, but not to limit, the invention. In the drawings, like reference characters denote corresponding features consistently throughout similar embodiments.

[0019] **FIG. 1A** is an exploded cross-sectional view of an applicator for applying an on-skin assembly to skin of a host including a sealing element, in accordance with some embodiments.

[0020] **FIG. 1B** is a zoomed cutaway view of the applicator of **FIG. 1A**, further illustrating an insertion assembly and the on-skin assembly, in accordance with some embodiments.

[0021] **FIG. 1C** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a sealing element having a frangible member, in accordance with some embodiments.

[0022] **FIG. 2A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a peelable tamper indicator, in accordance with some embodiments.

[0023] **FIG. 2B** is a partially exploded perspective view of the applicator of **FIG. 2A**.

[0024] **FIG. 3A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including another tamper indicator, in accordance with some embodiments.

[0025] **FIG. 3B** is a zoomed cross-sectional view of the applicator of **FIG. 3A**, wherein a sealing element comprises an o-ring, in accordance with some embodiments.

[0026] **FIG. 3C** is zoomed cross-sectional view of the applicator of **FIGs. 3A** and **3B**, in accordance with some embodiments.

[0027] **FIG. 4A** illustrates a perspective view of another applicator for applying an on-skin assembly to skin of a host including a tamper indicator, in accordance with some embodiments.

[0028] **FIG. 4B** is a partially exploded view of the applicator of **FIG. 4A**.

[0029] **FIG. 5A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a tactile indication of grip for the host, in accordance with some embodiments.

[0030] **FIG. 5B** is a partially exploded view of the applicator of **FIG. 5A**.

[0031] **FIG. 6A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a sealing element configured to couple with a housing in a single axial orientation, in accordance with some embodiments.

[0032] **FIG. 6B** is another perspective view of the applicator of **FIG. 6A**, shown with the sealing element separated from the housing

[0033] **FIG. 7A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a frangible member configured to prevent activation of an actuation member, in accordance with some embodiments.

[0034] **FIG. 7B** is a partially exploded view of the applicator of **FIG. 7A**.

[0035] **FIG. 8A** illustrates a perspective view of another applicator for applying an on-skin assembly to skin of a host including a frangible member configured to prevent activation of an actuation member, in accordance with some embodiments.

[0036] **FIG. 8B** is a cross-sectional view of the applicator of **FIG. 8A** in a pre-deployment configuration.

[0037] **FIG. 8C** is a cross-sectional view of the applicator of **FIG. 8A** in a deployed configuration.

[0038] **FIG. 9A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including an actuation member configured as a cap disposed over a housing of the applicator, in accordance with some embodiments.

[0039] **FIG. 9B** is a cross-sectional view of the applicator of **FIG. 9A** in a pre-deployment configuration.

[0040] **FIG. 9C** is a cross-sectional view of the applicator of **FIG. 9A** in a deployed configuration.

[0041] **FIG. 10A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a removable cap configured as a sealing element, in accordance with some embodiments.

[0042] **FIG. 10B** is a partially exploded view of the applicator of **FIG. 10A**.

[0043] **FIG. 11A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a flexible member disposed over at least a portion of the applicator housing, in accordance with some embodiments.

[0044] **FIG. 11B** is a detail view of a portion of the flexible member of **FIG. 11A** disposed over an actuation member.

[0045] **FIG. 12A** illustrates a cross-sectional view of an applicator for applying an on-skin assembly to skin of a host including a flexible member having a bistable configuration that provides a visual indication of deployment, in accordance with some embodiments.

[0046] **FIG. 12B** is a detail cross-sectional view of a portion of the bistable configuration of the flexible member of **FIG. 12A**.

[0047] **FIG. 13A** is an exploded view of an applicator for applying an on-skin assembly to skin of a host including a frangible member configured to cover an actuation member, in accordance with some embodiments.

[0048] **FIG. 13B** is an assembled view of the applicator of **FIG 13A**.

[0049] **FIG. 13C** illustrates a perspective view of the applicator of **FIG. 13A** and **13B** having the frangible member removed, thereby exposing an actuation member.

[0050] **FIG. 14** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a frangible portion having a flexible tab molded around an actuation member, in accordance with some embodiments.

[0051] **FIG. 15A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a peelable layer configured to seal a distal opening in a housing and to further seal an actuation member, in accordance with some embodiments.

[0052] **FIG. 15B** illustrates the applicator of **FIG. 15A** having the peelable layer removed.

[0053] **FIG. 16A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a peelable layer configured to seal a distal opening in a housing, to further seal an actuation member, and to further seal vent permeable to a sterilizing gas, in accordance with some embodiments.

[0054] **FIG. 16B** is a partially exploded view of the applicator of **FIG. 16A**.

[0055] **FIG. 17A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a peelable layer configured to seal a distal opening in a housing and a inset plug configured to seal an actuation member, in accordance with some embodiments.

[0056] **FIG. 17B** illustrates the applicator of **FIG. 17A** with the inset plug removed.

[0057] **FIG. 17C** illustrates the applicator of **FIG. 17A** with the peelable layer at least partially removed.

[0058] **FIG. 18A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a removable cap configured to seal an actuation member and a peelable layer configured to seal a distal opening in a housing, in accordance with some embodiments.

[0059] **FIG. 18B** is a partially exploded view of the applicator of **FIG. 18A**.

[0060] **FIG. 19A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a frangible cap configured to seal an actuation member and a peelable layer configured to seal a distal opening in a housing, in accordance with some embodiments.

[0061] **FIG. 19B** is a partially exploded view of the applicator of **FIG. 19A**.

[0062] **FIG. 20A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a first peelable layer configured to seal a distal opening in a housing and a second peelable layer configured to seal an actuation member disposed in a proximal opening in the housing, in accordance with some embodiments.

[0063] **FIG. 20B** illustrates the actuation member of the applicator of **FIG. 20A**.

[0064] **FIG. 21A** illustrates a perspective view of another applicator for applying an on-skin assembly to skin of a host including a inset plug configured to seal an actuation member and a peelable layer configured to seal a distal opening in a housing, in accordance with some embodiments.

[0065] **FIG. 21B** is a detail view of the applicator of **FIG. 21A** having the peelable layer removed.

[0066] **FIG. 21C** is a detail view of the applicator of **FIG. 21A** having the inset cap removed.

[0067] **FIG. 22A** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host including a first peelable layer configured to seal a distal opening in a housing and to seal a vent permeable to a sterilizing gas and a second peelable layer configured to seal an actuation member disposed in a proximal opening in the housing, in accordance with some embodiments.

[0068] **FIG. 22B** is a partially exploded view of the applicator of **FIG. 22A**.

[0069] **FIG. 23** illustrates a perspective view of an applicator for applying an on-skin assembly to skin of a host configured to fit within a collapsible cup having a removable lid, in accordance with some embodiments.

[0070] **FIG. 24A** illustrates a perspective view of a cup having a removable lid and configured to enclose an applicator for applying an on-skin assembly to skin of a host, in accordance with some embodiments.

[0071] **FIG. 24B** is a cross-sectional view of the cup and applicator of **FIG. 24A**.

[0072] **FIG. 25A** is a cross-sectional view of an applicator for applying an on-skin assembly to skin of a host including an actuation member that is permeable to a sterilizing gas, in accordance with some embodiments.

[0073] **FIG. 25B** is a detail view of the actuation member of **FIG. 25A**.

[0074] **FIG. 26A** is a cross-sectional view of a soluble moisture barrier having a plurality of perforations for an applicator for applying an on-skin assembly to skin of a host, in accordance with some embodiments.

[0075] **FIG. 26B** is a cross-sectional view of the soluble moisture barrier of **FIG. 26A** after heating such that the moisture barrier has melted and the plurality of perforations are sealed.

[0076] **FIG. 27A** is a cross-sectional view of a moisture barrier including an elastomeric layer having a portion permeable to a sterilizing gas and a perforated layer configured to pass a permeable gas when the elastomeric layer and the perforated layer are in a first orientation with respect to each other, in accordance with some embodiments.

[0077] **FIG. 27B** is a cross-sectional view of the moisture barrier of **FIG. 27A** illustrating the elastomeric layer and the perforated layer in a second orientation with respect to each other such that the moisture barrier is impermeable to the sterilizing gas and to moisture, in accordance with some embodiments.

[0078] **FIG. 28A** illustrates a perspective view of a tray configured to hold a plurality of applicators for bulk sterilization and moisture barrier sealing, in accordance with some embodiments.

[0079] **FIG. 28B** is a detail view of the tray of **FIG. 28A** illustrating each applicator in a first configuration permeable to a sterilizing gas, and a second configuration impermeable to the sterilizing gas and to moisture.

[0080] **FIG. 29** is an exploded perspective view of a sealing element comprising a first layer permeable to a sterilizing gas and a second layer impermeable to the sterilizing gas and moisture, in accordance with some embodiments.

[0081] **FIG. 30A** is a zoomed cross-sectional view of a sealing element comprising a vent including a material permeable to a sterilizing gas, in accordance with some embodiments.

[0082] **FIG. 30B** is a zoomed cross-sectional view of the sealing element of **FIG. 30A** wherein at least a layer of the vent material is sintered thereby becoming impermeable to the sterilizing gas.

[0083] **FIG. 31** illustrates a schematic view of a continuous analyte sensor system, according to some embodiments.

[0084] **FIG. 32** is a flowchart illustrating a method of manufacturing an applicator for applying an on-skin assembly to skin of a host, in accordance with some embodiments.

[0085] **FIG. 33** is a flowchart illustrating another method of manufacturing an applicator for applying an on-skin assembly to skin of a host, in accordance with some embodiments.

DETAILED DESCRIPTION OF CERTAIN INVENTIVE EMBODIMENTS

[0086] The following description and examples illustrate some example embodiments of the disclosed invention in detail. Those of skill in the art will recognize that there are numerous variations and modifications of this invention that are encompassed by its scope. Accordingly, the description of a certain example embodiment should not be deemed to limit the scope of the present invention.

[0087] The present application is directed to embodiments of applicators for applying an on-skin assembly to skin of a host as well as methods of their manufacture and use. As will be described in more detail in connection with the figures below, certain features of the described

applicators provide novel and inventive solutions to difficulties associated with previous applicator designs and/or methods of their use or manufacture.

System Introduction

[0088] U.S. Patent Publication No. US-2013-0267811-A1, the entire contents of which are incorporated by reference herein, explains how **FIG. 31** is a schematic of a continuous analyte sensor system 3100 attached to a host (e.g., a person). The analyte sensor system 3100 communicates with other devices 3108-3114 (which can be located remotely from the host). A transcutaneous analyte sensor system 3100 comprising an on-skin sensor assembly 3106 is fastened to the skin of a host via a base (not shown), which can be a disposable housing.

[0089] The system 3100 includes a transcutaneous analyte sensor 3102 and an electronics unit (referred to interchangeably as "sensor electronics" or "transmitter") 3104 for wirelessly transmitting analyte information to a receiver. The receiver can be located remotely relative to the system 3100. In some embodiments, the receiver includes a display screen, which can display information to a person such as the host. Example receivers include computers such as dedicated display devices, mobile electronics, smartphones, smartwatches, tablet computers, laptop computers, and desktop computers. In some embodiments, receivers can be Apple Watches, iPhones, and iPads made by Apple Inc. Receivers may be running customized or stock operating systems such as, but not limited to, linux, iOS by Apple Inc., or Android by Google Inc.

[0090] In some embodiments, the receiver is mechanically coupled to the electronics unit 3104 to enable the receiver to receive data (e.g., analyte data) from the electronics unit 3104. To increase the convenience to users, in several embodiments, the receiver does not need to be mechanically coupled to the electronics unit 3104 and can even receive data from the electronics unit 3104 over great distances (e.g., when the receiver is many feet or even many miles from the electronics unit 3104).

[0091] During use, a sensing portion of the sensor 3102 can be under the host's skin and a contact portion of the sensor 3102 can be electrically connected to the electronics unit 3104. The electronics unit 3104 can be engaged with a housing (e.g., a base) or directly coupled to an adhesive patch fastened to the skin of the host.

[0092] The on-skin sensor assembly 3106 may be attached to the host with use of an applicator adapted to provide convenient and secure application. Such an applicator may also be used for attaching the electronics unit 3104 to a base, inserting the sensor 3102 through the host's skin, and/or connecting the sensor 3102 to the electronics unit 3104. Once the electronics unit 3104 is engaged with the base and the sensor 3102 has been inserted into the skin (and is connected to the electronics unit 3104), the sensor assembly can detach from the applicator.

[0093] The continuous analyte sensor system 3100 can include a sensor configuration that provides an output signal indicative of a concentration of an analyte. The output signal including (e.g., sensor data, such as a raw data stream, filtered data, smoothed data, and/or otherwise transformed sensor data) is sent to the receiver.

[0094] In some embodiments, the analyte sensor system 3100 includes a transcutaneous glucose sensor, such as is described in U.S. Patent Publication No. US-2011-0027127-A1, the entire contents of which are hereby incorporated by reference. In some embodiments, the sensor system 3100 includes a continuous glucose sensor and comprises a transcutaneous sensor (e.g., as described in U.S. Pat. No. 6,565,509, as described in U.S. Pat. No. 6,579,690, as described in U.S. Pat. No. 6,484,046). The contents of U.S. Pat. No. 6,565,509, U.S. Pat. No. 6,579,690, and U.S. Pat. No. 6,484,046 are hereby incorporated by reference in their entirety.

[0095] In several embodiments, the sensor system 3100 includes a continuous glucose sensor and comprises a refillable subcutaneous sensor (e.g., as described in U.S. Pat. No. 6,512,939). In some embodiments, the sensor system 3100 includes a continuous glucose sensor and comprises an intravascular sensor (e.g., as described in U.S. Pat. No. 6,477,395, as described in U.S. Pat. No. 6,424,847). The contents of U.S. Pat. No. 6,512,939, U.S. Pat. No. 6,477,395, and U.S. Pat. No. 6,424,847 are hereby incorporated by reference in their entirety.

[0096] Various signal processing techniques and glucose monitoring system embodiments suitable for use with the embodiments described herein are described in U.S. Patent Publication No. US-2005-0203360-A1 and U.S. Patent Publication No. US-2009-0192745-A1, the contents of which are hereby incorporated by reference in their entirety. The sensor can extend through a housing, which can maintain the sensor on the skin and can provide for electrical connection of the sensor to sensor electronics, which can be provided in the electronics unit 3104.

[0097] One or more repeaters, receivers and/or display devices, such as a key fob repeater 3108, a medical device receiver 3110 (e.g., an insulin delivery device and/or a dedicated glucose sensor receiver), a smartphone 3112, a portable computer 3114, and the like can be communicatively coupled to the electronics unit 3104 (e.g., to receive data from the electronics unit 3104). The electronics unit 3104 can also be referred to as a transmitter. In some embodiments, the devices 3108-3114 transmit data to the electronics unit 3104. The sensor data can be transmitted from the sensor electronics unit 3104 to one or more of the key fob repeater 3108, the medical device receiver 3110, the smartphone 3112, the portable computer 3114, and the like. In some embodiments, analyte values are displayed on a display device.

[0098] The electronics unit 3104 may communicate with the devices 3108-3114, and/or any number of additional devices, via any suitable communication protocol. Example communication protocols include radio frequency; Bluetooth; universal serial bus; any of the wireless local area network (WLAN) communication standards, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols; ZigBee; wireless (e.g., cellular) telecommunication; paging network communication; magnetic induction; satellite data communication; and/or a proprietary communication protocol.

[0099] Additional sensor information is described in U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201. The entire contents of U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201 are incorporated by reference herein.

[0100] Any sensor shown or described herein can be an analyte sensor; a glucose sensor; and/or any other suitable sensor. A sensor described in the context of any embodiment can be any sensor described herein or incorporated by reference, such as an analyte sensor; a glucose sensor; any sensor described herein; and any sensor incorporated by reference. Sensors shown or described herein can be configured to sense, measure, detect, and/or interact with any analyte.

[0101] As used herein, the term "analyte" is a broad term, and is to be given its ordinary and customary meaning to a person of ordinary skill in the art (and is not to be limited to a special or customized meaning), and refers without limitation to a substance or chemical constituent in a biological fluid (for example, blood, interstitial fluid, cerebral spinal fluid, lymph fluid, urine, sweat, saliva, etc.) that can be analyzed. Analytes can include naturally occurring substances, artificial substances, metabolites, or reaction products.

[0102] In some embodiments, the analyte for measurement by the sensing regions, devices, systems, and methods is glucose. However, other analytes are contemplated as well, including, but not limited to ketone bodies; Acetyl Co A; acarboxyprothrombin; acylcarnitine; adenine phosphoribosyl transferase; adenosine deaminase; albumin; alpha-fetoprotein; amino acid profiles (arginine (Krebs cycle), histidine/urocanic acid, homocysteine, phenylalanine/tyrosine, tryptophan); andrenostenedione; antipyrine; arabinitol enantiomers; arginase; benzoylecgonine (cocaine); biotinidase; biopterin; c-reactive protein; carnitine; carnosinase; CD4; ceruloplasmin; chenodeoxycholic acid; chloroquine; cholesterol; cholinesterase; cortisol; testosterone; choline; creatine kinase; creatine kinase MM isoenzyme; cyclosporin A; d-penicillamine; de-ethylchloroquine; dehydroepiandrosterone sulfate; DNA (acetylator polymorphism, alcohol dehydrogenase, alpha 1-antitrypsin, cystic fibrosis, Duchenne/Becker muscular dystrophy, glucose-6-phosphate dehydrogenase, hemoglobin A, hemoglobin S, hemoglobin C, hemoglobin D, hemoglobin E, hemoglobin F, D-Punjab, beta-thalassemia, hepatitis B virus, HCMV, HIV-1, HTLV-1, Leber hereditary optic neuropathy, MCAD, RNA, PKU, Plasmodium vivax, sexual differentiation, 21-deoxycortisol); desbutylhalofantrine; dihydropteridine reductase; diptheria/tetanus antitoxin; erythrocyte arginase; erythrocyte protoporphyrin; esterase D; fatty acids/acylglycines; triglycerides; glycerol; free ß-human chorionic gonadotropin; free erythrocyte porphyrin; free thyroxine (FT4); free tri-iodothyronine (FT3); fumarylacetoacetase; galactose/gal-1-phosphate; galactose-1-phosphate uridyltransferase; gentamicin; glucose-6-phosphate dehydrogenase; glutathione; glutathione perioxidase; glycocholic acid; glycosylated hemoglobin; halofantrine; hemoglobin variants; hexosaminidase A; human erythrocyte carbonic anhydrase I; 17-alpha-hydroxyprogesterone; hypoxanthine phosphoribosyl transferase; immunoreactive trypsin; lactate; lead; lipoproteins ((a), B/A-1, ß); lysozyme; mefloquine; netilmicin; phenobarbitone; phenytoin; phytanic/pristanic acid; progesterone; prolactin; prolidase; purine nucleoside phosphorylase; quinine; reverse tri-iodothyronine (rT3); selenium; serum pancreatic lipase; sissomicin; somatomedin C; specific antibodies (adenovirus, anti-nuclear antibody, anti-zeta antibody, arbovirus, Aujeszky's disease virus, dengue virus, Dracunculus medinensis, Echinococcus granulosus, Entamoeba histolytica, enterovirus, Giardia duodenalisa, Helicobacter pylori, hepatitis B virus, herpes virus, HIV-1, IgE (atopic disease), influenza virus, Leishmania donovani, leptospira, measles/mumps/rubella, Mycobacterium leprae, Mycoplasma pneumoniae, Myoglobin, Onchocerca volvulus,

parainfluenza virus, Plasmodium falciparum, poliovirus, Pseudomonas aeruginosa, respiratory syncytial virus, rickettsia (scrub typhus), Schistosoma mansoni, Toxoplasma gondii, Trepenoma pallidium, Trypanosoma cruzi/rangeli, vesicular stomatis virus, Wuchereria bancrofti, yellow fever virus); specific antigens (hepatitis B virus, HIV-1); acetone (e.g., succinylacetone); acetoacetic acid; sulfadoxine; theophylline; thyrotropin (TSH); thyroxine (T4); thyroxine-binding globulin; trace elements; transferrin; UDP-galactose-4-epimerase; urea; uroporphyrinogen I synthase; vitamin A; white blood cells; and zinc protoporphyrin.

[0103] Salts, sugar, protein, fat, vitamins, and hormones naturally occurring in blood or interstitial fluids can also constitute analytes in certain embodiments. The analyte can be naturally present in the biological fluid or endogenous, for example, a metabolic product, a hormone, an antigen, an antibody, and the like. Alternatively, the analyte can be introduced into the body or exogenous, for example, a contrast agent for imaging, a radioisotope, a chemical agent, a fluorocarbon-based synthetic blood, or a drug or pharmaceutical composition, including but not limited to insulin; glucagon; ethanol; cannabis (marijuana, tetrahydrocannabinol, hashish); inhalants (nitrous oxide, amyl nitrite, butyl nitrite, chlorohydrocarbons, hydrocarbons); cocaine (crack cocaine); stimulants (amphetamines, methamphetamines, Ritalin, Cylert, Preludin, Didrex, PreState, Voranil, Sandrex, Plegine); depressants (barbiturates, methaqualone, tranquilizers such as Valium, Librium, Miltown, Serax, Equanil, Tranxene); hallucinogens (phencyclidine, lysergic acid, mescaline, peyote, psilocybin); narcotics (heroin, codeine, morphine, opium, meperidine, Percocet, Percodan, Tussionex, Fentanyl, Darvon, Talwin, Lomotil); designer drugs (analogs of fentanyl, meperidine, amphetamines, methamphetamines, and phencyclidine, for example, Ecstasy); anabolic steroids; and nicotine. The metabolic products of drugs and pharmaceutical compositions are also contemplated analytes. Analytes such as neurochemicals and other chemicals generated within the body can also be analyzed, such as, for example, ascorbic acid, uric acid, dopamine, noradrenaline, 3-methoxytyramine (3MT), 3,4-dihydroxyphenylacetic acid (DOPAC), homovanillic acid (HVA), 5-hydroxytryptamine (5HT), 5-hydroxyindoleacetic acid (FHIAA), and intermediaries in the Citric Acid Cycle.

[0104] Many embodiments described herein use an adhesive. One purpose of the adhesive can be to couple a base, a sensor module, and/or a sensor to a host (e.g., to skin of the host). The adhesive can be configured for adhering to skin. The adhesive can include a pad

(e.g., that is located between the adhesive and the base). Additional adhesive information, including adhesive pad information, is described in U.S. Patent Application No. 14/835,603, which was filed on August 25, 2015. The entire contents of U.S. Patent Application No. 14/835,603 are incorporated by reference herein.

Sterilization and Sealing of Applicators

[0105] Any time a foreign structure comes in contact with the human body there is a potential for infection, which can lead to serious health consequences. Thus, sterilization of an applicator (and/or of the portions of an applicator that come in contact with, or that are inserted into, a body part of the host) are not only desirable, but required in many circumstances. Various sterilization methods can be used in embodiments, including but not limited to heat sterilization, gamma sterilization, electron beam sterilization, and gas (e.g. ethylene oxide) sterilization. In embodiments adapted for gas sterilization, an applicator can be configured with one or more apertures, at least during one or more steps of manufacture, which are configured to allow ingress and egress of gas during one or more sterilization steps. In addition, it may be desirable to seal applicators from ingress of moisture (e.g., water vapor) in some embodiments. Moisture, especially water vapor, can corrode (e.g., rust, tarnish) any metallic parts within an applicator, for example, a needle, a spring, or any other metallic structure. Such corrosion coming in contact with the host, especially where a needle enters the skin of a host, can cause serious health consequences. Moisture can also promote growth of infectious agents and provide a medium for their proliferation, causing serious health consequences. The present application provides various embodiments of applicators that are gas sterilizable and/or include a moisture (e.g., water vapor) seal, for example, through the use of one or more removable caps on the top (e.g., proximal) or bottom (e.g., distal) ends of the applicator, through one or more trigger mechanisms comprising integrated caps, through one or more sealing layers that cover one or more orifices, apertures or vents of the applicator, through sterilizable gas-permeable polymers, through sterilizable gas-permeable trigger mechanisms, through protective cups, or any combinations of the same, as will be described in more detail in connection with at least some of **FIGs. 1A-33** below.

Safety Features of Applicators

[0106] Consumers may find it desirable to use applicators that provide particular safety features. For example, tamper evident sealing or other tamper evidence features may be desirable because such features allow a consumer to identify when an applicator has been previously used or containment has been breached and, thus, avoid using an applicator that may be faulty or pose an increased health risk if used. Examples of tamper evidence features are described in more detail in connection with at least some of **FIGs. 1A-33** below.

[0107] In addition, especially in the case of disposable applicators, it can be frustrating or dangerous to have an applicator deploy prematurely or unexpectedly. Thus, consumers may find it desirable for applicators to include premature deployment prevention features to substantially reduce or prevent the occurrence of premature activation. Examples of premature deployment prevention features are described in more detail in connection with at least some of **FIGs. 1A-33** below.

[0108] In line with premature deployment prevention features, it may be desirable to provide features which minimize the risk of unintended activation when the applicator is dropped. For example, an exposed trigger mechanism may be accidentally activated if the applicator is dropped on the exposed trigger mechanism. However, in some cases, the shock of dropping the applicator itself can cause accidental activation of the applicator even where there is no exposed trigger mechanism. Examples of drop protection features and other premature deployment prevention features are described in more detail in connection with at least some of **FIGs. 1A-33** below.

Bulk Manufacturing and/or Sterilization

[0109] The cost of manufacture of applicators is a concern for the manufacturer as well as for the consumer. In general, the less expensive it is to produce an applicator, the lower the cost it is to the consumer. Thus, it is desirable to provide bulk manufacturing, sterilizing and/or sealing of applicators. Examples of applicator configurations and methods of bulk sterilizing and/or sealing of applicators include, but are not limited to, melting, chemically altering, or physically altering a vent, plug, feature, or layer such that it transforms from a state of being permeable to a sterilizing gas and/or moisture (e.g., water vapor) to impermeable to the sterilizing gas and/or moisture, as will be described in more detail in connection with at least some of **FIGs. 1A-33** below.

Easy and Repositionable Deployment

[0110] Consumers may additionally find it desirable to easily position (and reposition if desired) an applicator in a particular location on the body, optionally using only a single hand, without necessarily requiring a complete view of the applicator as it is held in the desired location. Such easy single-handed deployment may be achieved through the provision of various orientations and forms of actuation members, as well as the use of one or more raised or recessed portions configured as tactile grips and/or orientation indicators, as will be described in more detail in connection with at least some of **FIGs. 1A-33** below. Consumers may also find it desirable to be able to reposition the applicator prior to activation even after it has been first placed on the body, without comprising the integrity of the applicator and/or any adhesive provided thereon.

Embodiments Including a Removable Cap

[0111] Some embodiments can include a removable cap configured to function as a sterilization seal and/or as a moisture barrier. For example, **FIG. 1A** is an exploded, cutaway view of an applicator 100 for applying an on-skin assembly 102 to skin of a host including a sealing element 110, in accordance with some embodiments. Applicator 100 comprises a housing 104 configured to house an insertion assembly 118 (see **FIG. 1B**). Housing 104 comprises an aperture 106 through which on-skin assembly 102 (see **FIG. 1B**) is configured to pass during deployment. The side of housing 104 may further comprise an opening 120 configured to receive an actuation member (not shown in **FIGs. 1A-1C**). Such an actuation member can be configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly 102 into the skin of a host. The actuation member is disposed on a side of housing 104 in the region of the opening 120. By providing an actuation member on a side of housing 104, applicator 100 may provide for easy single-handed deployment of on-skin assembly 102 to the skin of a host.

[0112] Housing 104 further comprises an optional flexible wall 128 configured to absorb at least a portion of energy imparted to applicator 100 when applicator 100 is dropped. By absorbing energy that might otherwise transfer a physical shock to applicator 100, flexible wall 128 may provide a premature deployment prevention and drop protection feature.

[0113] Applicator 100 further comprises a sealing element 110 configured to provide a sterile barrier and/or a vapor barrier between an internal environment of housing 104 and an external environment of housing 104. As shown in **FIG. 1A**, sealing element 110 comprises a removable cap 112 configured to couple with a portion of housing 104. Specifically, and as an example, removable cap 112 is configured to couple with a distal portion of housing 104 via threads 114. For example, threads 114 disposed on removable cap 112 may be configured to mate with threads 108 disposed on housing 104. Removable cap 112 may be detached from housing 104 by twisting removable cap 112 with respect to housing 104, or vice versa, until threads 114 and threads 108 are no longer mated with each other, and then pulling housing 104 and removable cap 112 apart. Sealing element 110 may additionally comprise retention element 138 between removable cap 112 and housing 104 before removal of removable cap 112. As shown, removable cap 112 covers the actuation member by virtue of the actuation member being disposed on a side of housing 104. Sealing element 110 may further comprise a first layer 122 that is permeable to a sterilizing gas (e.g., ethylene oxide, or ETO). First layer 122 may comprise Tyvek® material, although any other material permeable to a sterilizing gas may be utilized. Application of first layer 122 to removable cap 112 may allow for the ingress and egress of a sterilizing gas during manufacture. Sealing element 110 may further comprise a second layer 124 that is substantially impermeable to moisture (e.g., water vapor). Second layer 124 may comprise a metallic foil, although any suitable material impermeable to moisture (e.g., water vapor) may be utilized, for example, a metallic foil (e.g., aluminum or titanium), a metallic substrate, an aluminum oxide coated polymer, parylene, a polymer coated with a metal applied via vapor metallization, a silicon dioxide coated polymer, or any material having a moisture vapor transmission rate less than 10 grams/100in^2 or preferably less than 1 gram/100in^2. First layer 122 and second layer 124 may seal an opening 126 in the bottom of removable cap 112. Application of second layer 124 over first layer 122 after sterilization may further maintain sterility via the first layer and add a moisture barrier via the second layer. Together, the above-described features of sealing element 110 may provide joint sterilization and moisture sealing of applicator 100.

[0114] The applicator 100 further includes a support member 116 configured to inhibit at least lateral movement of insertion assembly 118. In some embodiments, support member 116 may comprise an elastomeric membrane, film, bulk elastomer, foam, or rigid structure.

Furthermore, support member 116 can maintain the insertion assembly 118 in position during deleterious movement such as a drop or vibration.

[0115] **FIG. 1B** is a zoomed cutaway view of applicator 100 of **FIG. 1A**, further illustrating at least insertion assembly 118 and on-skin assembly 102, in accordance with some embodiments. As shown in more detail in **FIG. 1B**, insertion assembly 118 may comprise a needle 140, for example, a C-needle configured to hold at least a portion of a sensor. In some embodiments, insertion assembly 118 may be configured to drive needle 140 utilizing a spring force. In some embodiments, insertion assembly 118 may additionally or alternatively be configured to retract needle 140 after on-skin assembly 102 has been deployed to the skin of the host.

[0116] In some embodiments, insertion assembly 118 may include substantially similar components and/or mechanisms from insertion assembly 118 of FIG. 8A-8C. In other embodiments, insertion assembly 118 may include substantially similar components from insertion assemblies described in U.S. Patent App. No. 15/387088, which is incorporated herein by reference it its entirety. For non-limiting example, insertion assembly 118 may include substantially similar components and/or mechanisms from telescoping assembly 132 of FIGS. 7-11, telescoping assembly 132b of FIGS. 56-58, telescoping assembly 132c and 132d of FIGS. 28-30, telescoping assembly 132e of FIG. 31, telescoping assembly 132f of FIG. 59, telescoping assembly 132g of FIGS. 44-45, telescoping assembly 132h of FIG. 60, telescoping assembly 132i of FIG. 48-50, telescoping assembly 132k of FIGS. 61-64, telescoping assembly 132m of FIGS. 71-74, telescoping assembly 132n of FIGS. 76-79, telescoping assembly 132p of FIGS. 80-85, telescoping assembly 132q of FIGS. 86-88, telescoping assembly 132r of FIGS. 89-91, telescoping assembly 132s of FIGS. 92-100, or telescoping assembly 132w of FIGS. 110-119, respectively described in U.S. Patent App. No. 15/387088.

[0117] Applicator 100 further comprises a transcutaneous on-skin analyte sensor assembly (referred to as an "on-skin assembly") 102 and an electronics unit (referred to as a "transmitter") 134 for wirelessly transmitting analyte information to a receiver (not shown). Before deployment, a sensor 132 of on-skin assembly 102 may be disposed on or at least partially in needle 140. During use, sensor 132 is disposed under the host's skin and a contact portion of on-skin assembly 102 is electrically connected to transmitter 134. On-skin assembly 102 is attached to an adhesive layer 136 for fastening to the skin of the host.

[0118] On-skin assembly 102 may be attached to the host with use of applicator 100 adapted to provide convenient and secure application. Applicator 100 may also be used for inserting at least a portion of on-skin assembly 102 through the host's skin. Once the portion of on-skin assembly 102 has been inserted, applicator 100 detaches from on-skin assembly 102.

[0119] In general, on-skin assembly 102 includes any sensor configuration that provides an output signal indicative of a concentration of an analyte, for example, blood glucose. The output signal including, e.g., sensor data, such as a raw data stream, filtered data, smoothed data, and/or otherwise transformed sensor data, is sent to a receiver which may be e.g., a smart phone, smart watch, dedicated device and the like. In some embodiments, sensor 132 comprises a transcutaneous glucose sensor, such as is described in US Patent Publication No. US-2011-0027127-A1, the contents of which are hereby incorporated by reference in its entirety. In some embodiments, sensor 132 is a continuous glucose sensor and comprises a transcutaneous sensor such as described in U.S. Patent 6,565,509 to Say et al., for example. In another embodiment, sensor 132 is a continuous glucose sensor and comprises a subcutaneous sensor such as described with reference to U.S. Patent 6,579,690 to Bonnecaze et al. or U.S. Patent 6,484,046 to Say et al., for example. In some other embodiments, sensor 132 is a continuous glucose sensor and comprises a subcutaneous sensor such as described with reference to U.S. Patent 6,512,939 to Colvin et al. In yet other embodiments, sensor 132 is a continuous glucose sensor and comprises an intravascular sensor such as described with reference to U.S. Patent 6,477,395 to Schulman et al., for example. In yet other embodiments, sensor 132 is a continuous glucose sensor and comprises an intravascular sensor such as described with reference to U.S. Patent 6,424,847 to Mastrototaro et al. Other signal processing techniques and glucose monitoring system embodiments suitable for use with the embodiments described herein are described in U.S. Patent Publication No. US-2005-0203360-A1 and U.S. Patent Publication No. US-2009-0192745-A1, the contents of which are hereby incorporated by reference in their entireties.

[0120] In still further embodiments, applicator 100 can be configured for use in applying a drug delivery device, such an infusion device, to the skin of a patient. In such embodiments, applicator 100 can include a catheter instead of, or in addition to, a sensor, the catheter being connected to an infusion pump configured to deliver liquid medicines or other fluids into the patient's body. In embodiments, the catheter can be deployed into the skin in much the same manner as a sensor would be, for example as described herein.

[0121] In some embodiments, sensor 132 is formed from a wire or is in a form of a wire. For example, sensor 132 can include an elongated conductive body, such as a bare elongated conductive core (e.g., a metal wire) or an elongated conductive core coated with one, two, three, four, five, or more layers of material, each of which may or may not be conductive. The elongated sensor may be long and thin, yet flexible and strong. For example, in some embodiments, the smallest dimension of the elongated conductive body is less than about 0.1 inches, less than about 0.075 inches, less than about 0.05 inches, less than about 0.025 inches, less than about 0.01 inches, less than about 0.004 inches, or less than about 0.002 inches. Sensor 132 may have a circular cross-section. In some embodiments, the cross-section of the elongated conductive body can be ovoid, rectangular, triangular, polyhedral, star-shaped, C-shaped, T-shaped, X-shaped, Y-Shaped, irregular, or the like. In some embodiments, a conductive wire electrode is employed as a core. To such a clad electrode, one or two additional conducting layers may be added (e.g., with intervening insulating layers provided for electrical isolation). The conductive layers can be comprised of any suitable material. In certain embodiments, it can be desirable to employ a conductive layer comprising conductive particles (i.e., particles of a conductive material) in a polymer or other binder.

[0122] In certain embodiments, the materials used to form the elongated conductive body (e.g., stainless steel, titanium, tantalum, platinum, platinum-iridium, iridium, certain polymers, and/or the like) can be strong and hard, and therefore are resistant to breakage. For example, in some embodiments, the ultimate tensile strength of the elongated conductive body is from about 80 kPsi to about 500 kPsi. In another example, in some embodiments, the Young's modulus of the elongated conductive body is from about 160 GPa to about 220 GPa. In still another example, in some embodiments, the yield strength of the elongated conductive body is from about 60 kPsi to about 2200 kPsi. In some embodiments, sensor's 132 small diameter provides (e.g., imparts, enables) flexibility to these materials, and therefore to sensor 132 as a whole. Thus, sensor 132 can withstand repeated forces applied to it by surrounding tissue.

[0123] In addition to providing structural support, resiliency and flexibility, in some embodiments, the core (or a component thereof) provides electrical conduction for an electrical signal from the working electrode to sensor electronics (not shown). In some embodiments, the core comprises a conductive material, such as stainless steel, titanium, tantalum, a conductive polymer, and/or the like. However, in other embodiments, the core is formed from a non-

conductive material, such as a non-conductive polymer. In yet other embodiments, the core comprises a plurality of layers of materials. For example, in some embodiments the core includes an inner core and an outer core. In a further embodiment, the inner core is formed of a first conductive material and the outer core is formed of a second conductive material. For example, in some embodiments, the first conductive material is stainless steel, titanium, tantalum, a conductive polymer, an alloy, and/or the like, and the second conductive material is conductive material selected to provide electrical conduction between the core and the first layer, and/or to attach the first layer to the core (e.g., if the first layer is formed of a material that does not attach well to the core material). In another embodiment, the core is formed of a non-conductive material (e.g., a non-conductive metal and/or a non-conductive polymer) and the first layer is a conductive material, such as stainless steel, titanium, tantalum, a conductive polymer, and/or the like. The core and the first layer can be of a single (or same) material, e.g., platinum. One skilled in the art appreciates that additional configurations are possible.

[0124] In some embodiments, transmitter 134 is incorporated into on-skin assembly 102, while in other embodiments, the transmitter 134 can be releasably coupled to the sensor. Transmitter 134 includes electronic circuitry associated with measuring and processing the continuous analyte sensor data, and is configured to perform algorithms associated with processing and calibration of the sensor data. For example, transmitter 134 can provide various aspects of the functionality of a sensor electronics module as described in U.S. Patent Publication No. 2009-0240120-A1 and U.S. Patent Publication No. 2012-0078071-A1 the contents of which are hereby incorporated by reference in their entireties. Transmitter 134 may include hardware, firmware, and/or software that enable measurement of levels of the analyte *via* a glucose sensor, such as an analyte on-skin assembly 102. For example, transmitter 134 can include a potentiostat, a power source for providing power to on-skin assembly 102, other components useful for signal processing and data storage, and preferably a telemetry module for one- or two-way data communication between transmitter 134 and one or more receivers, repeaters, and/or display devices. Electronics can be affixed to a printed circuit board (PCB), or the like, and can take a variety of forms. For example, the electronics can take the form of an integrated circuit (IC), such as an Application-Specific Integrated Circuit (ASIC), a microcontroller, and/or a processor. Transmitter 134 may include sensor electronics that are configured to process sensor information, such as storing data, analyzing data streams, calibrating analyte sensor data,

estimating analyte values, comparing estimated analyte values with time corresponding measured analyte values, analyzing a variation of estimated analyte values, and the like. Examples of systems and methods for processing sensor analyte data are described in more detail herein and in U.S. Patent No. 7,310,544, U.S. Patent No. 6,931,327, U.S. Patent Publication No. 2005-0043598-A1, U.S. Patent Publication No. 2007-0032706-A1, U.S. Patent Publication No. 2007-0016381-A1, U.S. Patent Publication No. 2008-0033254-A1, U.S. Patent Publication No. 2005-0203360-A1, U.S. Patent Publication No. 2005-0154271-A1, U.S. Patent Publication No. 2005-0192557-A1, U.S. Patent Publication No. 2006-0222566-A1, U.S. Patent Publication No. 2007-0203966-A1 and U.S. Patent Publication No. 2007-0208245-A1, the contents of which are hereby incorporated by reference in their entireties.

[0125] One or more repeaters, receivers and/or display devices, such as a medical device receiver (e.g., insulin delivery device and/or dedicated glucose sensor receiver), smart phone, portable computer, and the like may be operatively linked to and receive data from transmitter 134, and in some embodiments transmit data to transmitter 134.

[0126] In some embodiments, analyte values are displayed on a display device. In some embodiments, prompts or messages can be displayed on the display device to convey information to the user, such as reference outlier values, requests for reference analyte values, therapy recommendations, deviation of the measured analyte values from the estimated analyte values, or the like. Additionally, prompts can be displayed to guide the user through calibration or trouble-shooting of the calibration.

[0127] Although not necessarily shown in other **FIGs.**, any applicator described in this specification may include insertion assembly 118 and on-skin assembly 102 as described in connection with **FIGs. 1A** and **1B**.

[0128] Applicator 100 may further comprise a tamper indicator 130, specifically, a tamper-evident ring configured to break away from removable cap 112 when removable cap 112 is twisted with respect to housing 104. In this way, tamper indicator 130 may provide a safety feature for a host using applicator 100 such that if the tamper-evident ring is broken, tampering would be visually evident to a user.

[0129] **FIG. 1C** illustrates another applicator 150 for applying on-skin assembly 102 to skin of a host including a sealing element 160 having a frangible member 164, in accordance with some other embodiments. Applicator 150 may comprise all features previously described in

connection with applicator 100 of **FIGs. 1A** and **1B** except, instead of utilizing threads 114 and 108, sealing element 160 comprises a removable cap 162 configured to couple with a distal portion of housing 104 via frangible member 164. In some embodiments, frangible member 164 comprises a loop and a circumferential frangible portion configured to be removed by pulling on the loop. In this way, sealing element 160, including removable cap 162 and frangible member 164, may maintain sterilization and simultaneously provide a moisture seal for elements within housing 104. Frangible member 164 may prevent sealing cap 162 from being removed without also removing frangible member 164. Frangible member 164 further provides a tamper indicator and safety feature for a host using applicator 150 such that if the frangible member 164 is broken, tampering would be visually evident to a user.

[0130] **FIG. 2A** illustrates a perspective view of an applicator 200 for applying on-skin assembly 102 to skin of a host including a peelable tamper indicator 230, in accordance with some embodiments. Applicator 200 may comprise all features previously described in connection with applicator 100 of **FIGs. 1A** and **1B** except those specifically indicated as not being present below. For example, although not shown, applicator 200 may further include at least insertion assembly 118 and on-skin assembly 102 as described in connection with **FIGs. 1A-1C**.

[0131] Applicator 200 comprises a housing 204, a sealing element 210 comprising a removable cap 212, and peelable tamper indicator 230. Housing 204 may not include flexible wall 128 or threads 108 as previously described in connection with **FIGs. 1A** and **1B**. Likewise, removable cap 212 may not include threads 114. However, removable cap 212 may comprise at least one protrusion 220 or flattened (e.g., substantially planar) section configured to inhibit rolling of applicator 200 and to provide an orientation indicator for the user. Removable cap 212 may be detached from housing 204 by peeling off peelable tamper indicator 230 and pulling apart removable cap 212 and housing 204. Thus, if peelable tamper indicator 230 has been disturbed, tampering would be visually evident to a user.

[0132] **FIG. 2B** is a partially exploded view of applicator 200 of **FIG. 2A**. As shown more clearly in **FIG. 2B**, applicator 200 may further comprise an actuation member 250 (e.g., a push button) configured to, upon activation, cause insertion assembly 118 (see **FIG. 1B**) to insert at least a portion of on-skin assembly 102 (see **FIG. 1B**) into the skin of a host through aperture 106. Similar to **FIGs. 1A-1C**, removable cap 212 covers actuation member 250 by virtue of

actuation member 250 being disposed on a side of housing 204 and removable cap 212 covering a distal portion of housing 204 which shrouds actuation member 250. Shrouding actuation member 250 in this manner may prevent accidental activation. Sealing element 210 may further comprise first layer 122 and second layer 124, as previously described in connection with **FIG. 1B**. First layer 222 and second layer 224 may be disposed over one or more openings 226 in the bottom of removable cap 212. In some embodiments, the one or more openings 226 facilitate in sterilization and/or venting of the applicator 200. The above-described features of sealing element 210 may provide joint sterilization and moisture sealing for applicator 200.

[0133] **FIG. 3A** illustrates a perspective view of an applicator 300 for applying on-skin assembly 102 to skin of a host including a perforated tamper indicator tab 330, in accordance with some embodiments. Applicator 300 may comprise all features previously described in connection with applicator 100 of **FIGs. 1A** and **1B** except those specifically indicated as not being present below. For example, although not shown, applicator 300 may further include at least insertion assembly 118 and on-skin assembly 102 as described in connection with **FIGs. 1A-1C**.

[0134] Applicator 300 comprises a housing 304, a sealing element 310 comprising at least a removable cap 312, and adhesive mounted tamper indicator tab 330. Tamper indicator tab 330 may be adhesively backed paper, polymer, or other compatible film material. The tamper indicator tab 330 may further contain perforations, scoring, or deformed sections to guide removal of the tamper indicator tab 330. Housing 304 is further shown to include optional flexible wall 128 but may not include threads 108 as previously described in connection with **FIGs. 1A** and **1B**. Likewise, removable cap 312 may not include threads 114. Removable cap 312 may be detached from housing 304 by twisting and pulling apart removable cap 312 and housing 304. Any tampering with applicator 300 may result in the breaking of tamper indicator tab 330, providing visual evidence of tampering to a user.

[0135] **FIG. 3B** is a zoomed cutaway view of applicator 300 of **FIG. 3A**, in accordance with some embodiments. As shown, removable cap 312 and/or housing 304 may comprise retention element 138 as previously described in connection with **FIGs. 1A** and **1B**. Sealing element 310 may further comprise an O-ring 340 configured to provide a seal between removable cap 312 and housing 304. In some embodiments, O-ring 340 may be integrally molded together with either cap 312 or housing 304.

[0136] **FIG. 3C** is another zoomed cutaway view of applicator 300 of **FIGs. 3A** and **3B**, in accordance with some embodiments. As shown, the side of housing 304 may further comprise opening 120 configured to receive an actuation member (not shown in **FIGs. 3A-3C**), as previously described in connection with **FIGs. 1A** and **1B**. By providing an actuation member on a side of housing 304, applicator 300 may provide for easy single-handed deployment of on-skin assembly 102 (not shown in **FIG. 3C**) to the skin of a host.

[0137] **FIG. 3C** further illustrates opening 126 in the bottom of removable cap 312, as previously described in connection with **FIGs. 1A** and **1B**. Although not shown, sealing element 310 may further comprise first layer 122 and second layer 124 covering opening 126, as previously described in connection with **FIGs. 1A** and **1B**. Together, the above-described features of sealing element 310 may provide joint sterilization and moisture sealing of applicator 100.

[0138] **FIG. 4A** illustrates another applicator 400 for applying on-skin assembly 102 to skin of a host including a tamper indicator tab 330, in accordance with some embodiments. **FIG. 4B** is a partially exploded view of applicator 400 of **FIG. 4A**. Applicator 400 comprises substantially similar features of applicator 200 of **FIGs. 2A** and **2B**, however, replacing peelable tamper indicator 230 with tamper indicator tab 330 of **FIGs. 3A-3C**. As shown in FIG. 4B, applicator 400 may comprise the one or more openings 226 in the bottom of removable cap 212, as previously described in connection with at least FIG. 2B. First layer 122 and second layer 124 may cover the one or more openings 226.

[0139] **FIG. 5A** illustrates another applicator 500 for applying on-skin assembly 102 to skin of a host including a tactile indication of grip for the host, in accordance with some embodiments. **FIG. 5B** is a partially exploded view of applicator 500 of **FIG. 5A**. Applicator 500 comprises substantially all features of applicator 200 of **FIGs. 2A** and **2B**, however, replacing peelable tamper indicator 230 with a tamper-evident twist-off collar 530 and further including at least one set of one or more ridges or recesses 542, 544 configured to provide a tactile indication of grip to the host. For example, **FIGs. 5A** and **5B** show a housing 504, which may be substantially the same as housing 204 of **FIGs. 2A** and **2B**, however, further including a first set of one or more ridges or recesses 542 configured to provide a tactile indication of grip to the host. **FIGs. 5A** and **5B** further show a removable cap 512, which may be substantially the same as removable cap 212, however, further including a second set of one or more ridges or

recesses 544 configured to provide a tactile indication of grip to the host. As shown in FIG. 5BB, applicator 500 may comprise the one or more openings 226 in the bottom of removable cap 212, as previously described in connection with at least FIG. 2B. First layer 122 and second layer 124 may cover the one or more openings 226.

[0140] In addition, tamper-evident twist-off collar 530 is disposed at a mating location between housing 504 and removable cap 512. In some embodiments, a first portion 530a of tamper-evident twist-off collar 530 may be coupled to removable cap 512 and a second portion 530b of tamper-evident twist-off collar 530 may be coupled to housing 504. Removable cap 512 may be detached from housing 504 by twisting removable cap 512 with respect to housing 504, or vice versa, until first portion 530a breaks free of second portion 530b, and then pulling removable cap 512 and housing 504 apart. In its integral state, tamper-evident twist-off collar 530 may provide a seal (e.g., a sterile barrier and a moisture or water vapor barrier) between housing 504 and removable cap 512. In its separated state, tamper-evident twist-off collar 530 may provide an indication of tampering to a user.

[0141] **FIG. 6A** illustrates another applicator 600 for applying on-skin assembly 102 to skin of a host including a removable cap 612 configured to couple with a housing 604 in a single axial orientation, in accordance with some embodiments. **FIG. 6B** is a partially exploded view of applicator 600 of **FIG. 6A**. Applicator 600 comprises substantially all features of applicator 200 of **FIGs. 2A** and **2B**, however, not including peelable tamper indicator 230, including a removable cap 612 and a housing 604 both having shapes that couple in a single axial orientation and when combined limit rotation about the axis, and further including at least one set of one or more ridges or recesses 642, 644 configured to provide a tactile indication of grip to the host.

[0142] For example, **FIGs. 6A** and 6**B** show housing 604, which may be substantially the same as housing 204 of **FIGs. 2A** and **2B**, however, further including a first set of one or more ridges or recesses 642 configured to provide a tactile indication of grip to the host. Housing 604 may also include a visual indicator 608 located on a surface of housing 604 (as shown located on the top surface). Visual indicator 608 may be a slight protrusion or a slight indentation from the surface of the housing 604. Furthermore, visual indicator 608 may have a shape similar to the shape of the on-skin assembly 102. The orientation of visual indicator 608 may match with the orientation of on-skin assembly 102 within applicator 600. As such, visual indicator 608 may

assist in orienting the user to the orientation of the on-skin assembly 102 within the applicator 600 prior to deployment.

[0143] Housing 604 further has an irregularly shaped mating edge 652 that is not planar such that housing 604 will properly mate with removable cap 612 in a single axial orientation. Likewise, **FIGs. 6A** and **6B** further show removable cap 612, which may be substantially the same as removable cap 212, however, further including a second set of one or more ridges or recesses 644 configured to provide a tactile indication of grip to the host. Removable cap 612 further has an irregularly shaped mating edge 654 that is complementary in shape to the mating edge of housing 604 such that removable cap 612 will properly mate with housing 604 in the single axial orientation. Removable cap 612 may be detached from housing 604 by twisting removable cap 612 with respect to housing 604, or vice versa, and then pulling removable cap 612 and housing 604 apart. In some embodiments, the irregularly shaped mating edges 652, 654 of housing 604 and removable cap 612 also function as a tamper indication, since any tampering that causes relative displacement in any direction between removable cap 612 and housing 604 would cause their separation, thereby providing visual indication of tampering.

Embodiments Including a Top Cap Actuation member

[0144] Some embodiments can include an actuation member which is coupled to, or integrally formed with, a removable cap. For example, **FIG. 7A** illustrates a perspective view of an applicator 700 for applying on-skin assembly 102 to skin of a host including a frangible member as a safety configured to prevent activation of an actuation member, in accordance with some embodiments. **FIG. 7B** is a partially exploded view of applicator 700 of **FIG. 7A**. Although not shown, applicator 700 may further include insertion assembly 118 and on-skin assembly 102 as described in connection with **FIGs. 1A-1C** and as will be further described in connection with **FIGs. 8B** and **8C** below.

[0145] Applicator 700 comprises a housing 704 configured to house insertion assembly 118 (not shown) and comprises aperture 106 through which on-skin assembly 102 can pass. Housing 704 further comprises a vent 762 configured to be permeable to a sterilizing gas and able to maintain a sterile barrier. In some embodiments, vent 762 may be disposed on a top (i.e., proximal) side of housing 704. In some embodiments, a porous polymeric component is inserted into vent 762, for example, a Porex® plug. In some embodiments, second layer 124, as

previously described in connection with **FIGs. 1A** and **1B**, may be disposed directly over aperture 106 after sterilization, thereby providing a moisture barrier at the distal portion of housing 704.

[0146] In some embodiments, insertion assembly 118 and on-skin assembly 102 (not shown in detail in FIG. 7B) may be disposed within housing 704 and then second layer 124 may be disposed over aperture 106, thereby sealing the distal portion of housing 704. Ingress and egress of a sterilizing gas may then be achieved through vent 762, after which a sealing layer 764 may be disposed over vent 764 and a proximal portion of housing 704, thereby completely sealing an inside of housing 704 from an outside environment. Accordingly, in some embodiments, the combination of at least housing 704, second layer 124 and sealing layer 764 may form a sealing element configured to provide a sterile barrier and a vapor barrier between an internal environment and an external environment of housing 704.

[0147] Applicator 700 further comprises an actuation member 750 comprising a telescoping cap coupled to the proximal portion of housing 704. Accordingly, sealing layer 764 is disposed between the actuation member 750 (i.e., the cap) and housing 704. Actuation member 750 is configured to be activated by moving the cap in a distal direction. Accordingly, actuation member 750 may further comprise a protrusion 752 configured to pierce sealing layer 764 and thereby activate insertion assembly 118 (not shown) within housing 704 when the cap is moved in the distal direction. In some embodiments, actuation member 750 may be spring loaded such that pressure exceeding a threshold is required in order to move the cap in the distal direction sufficiently to activate actuation member 750.

[0148] Applicator 700 may further comprise a frangible safety member 766 configured to prevent activation of actuation member 750. In some embodiments, frangible safety member 766 is disposed between actuation member 750 and a distal portion of housing 704 such that frangible safety member 766 physically prevents movement of actuation member 750 at least until frangible safety member 766 is removed or sufficiently displaced. In this way, frangible safety member 766 simultaneously provides a premature deployment feature, a drop protection feature, and a tamper indication.

[0149] **FIG. 8A** illustrates another applicator 800 for applying on-skin assembly 102 to skin of a host including another frangible safety member 866 configured to prevent activation of an actuation member 850, in accordance with some embodiments. Applicator 800 is substantially

the same as application 700 previously described in connection with **FIGs. 7A** and **7B**, however, including a few similar features having slightly different shapes, excluding vent 764, and further illustrating a few additional features as described below.

[0150] For example, applicator 800 is shown to include housing 704 and second layer 124 as previously described in connection with **FIGs. 7A** and **7B**. Applicator 800 further comprises a frangible safety member 866 having substantially the same function and location as frangible safety member 766 of FIGs. 7A and 7B, however, having a substantially horizontal orientation rather than a substantially vertical orientation. Applicator 800 further comprises actuation member 850 comprising a telescoping cap coupled to the proximal portion of housing 704 and having substantially the same function as actuation member 750 but with a slightly different shape.

[0151] **FIG. 8B** is a cutaway view of applicator 800 of **FIG. 8A** in a pre-deployment configuration. FIG. 8B further illustrates insertion assembly 118 disposed within housing 704 and sealing layer 764. However, applicator 800 omits vent 764 and sealing layer 764 is instead disposed over an opening in a proximal portion of housing 704. Accordingly, in some embodiments, insertion assembly 118 and on-skin assembly 102 may be disposed within housing 704 and then second layer 124 may be disposed over aperture 106, thereby sealing the distal portion of housing 704. Ingress and egress of a sterilizing gas may then be achieved through the opening in the proximal portion of housing 704, after which sealing layer 764 may be disposed over the opening and over the proximal portion of housing 704, thereby completely sealing an inside of housing 704 from an outside environment. Accordingly, in some embodiments, the combination of at least housing 704, second layer 124 and sealing layer 764 may form a sealing element configured to provide a sterile barrier and a vapor barrier between an internal environment and an external environment of housing 704.

[0152] **FIG. 8B** further illustrates protrusion 752 of actuation member 850 in a position ready to pierce sealing layer 764 when actuation member 850 (e.g., telescoping cap) is moved in a distal direction. Applicator 800 is further illustrated as including a spring feature 854 (e.g. molded or integrated spring feature) configured to provide the biased force loaded aspect of the actuation member 850 as previously described in connection with **FIGs. 7A** and **7B**.

[0153] **FIG. 8C** is a cutaway view of applicator 800 of **FIG. 8A** in a deployed configuration. As shown, second layer 124 has been removed before deployment and actuation

member 850 is shown as having been moved in the distal direction, causing protrusion 752 to pierce sealing layer 764 and activate insertion assembly 118.

[0154] **FIG. 9A** illustrates another applicator 900 for applying on-skin assembly 102 to skin of a host including an actuation member 950 configured as a cap disposed over housing 704 of applicator 900, in accordance with some embodiments. Applicator 900 is substantially similar to applicator 800 previously described in connection with **FIGs. 8A-8C**, except as described below. As shown in **FIG. 9A**, applicator 900 includes housing 704, second layer 124 sealing aperture 106 (not shown) of housing 704 and sealing layer 764 disposed on proximal portion of housing 704. Applicator 900 further comprises actuation member 950 comprising a cap coupled to the proximal portion of housing 704. Actuation member 950 comprises protrusion 752, which is configured to pierce sealing layer 764 during activation of actuation member 950. The cap forming actuation member 950 may further comprise a side flexure 956 configured to unlock actuation member 950. Specifically, moving side flexture 956 allows the actuation member 950 to move in a distal direction arms. Activation member 950 further moves protrusion 752 such that it pierces sealing layer 764 and activates insertion assembly 118 (not shown, see **FIGs. 8B** and **8C**). Furthermore, applicator 900 may not include spring feature 854, but instead comprises a spring feature 954 disposed on a side of housing 704 between housing 704 and the cup of actuation member 950, which may provide substantially the same effect as spring feature 854. In some embodiments, spring feature 954 may be coupled to housing 704 at one end and coupled to the cup forming actuation member 950 at the other end. Actuation member 950 may provide additional premature deployment prevention and drop protection features.

[0155] **FIG. 9B** further illustrates protrusion 752 of actuation member 950 in a position ready to pierce sealing layer 764 when actuation member 950 (e.g., telescoping cap) is moved in a distal direction. Applicator 900 is further illustrated as including the spring feature 954 configured to provide the biased force loaded aspect of the actuation member 950 as previously described.

[0156] **FIG. 9C** is a cutaway view of applicator 900 of **FIG. 9A** in a deployed configuration. As shown, second layer 124 has been removed before deployment and actuation member 950 is shown as having been moved in the distal direction and side flexure 956 depressed, causing protrusion 752 to pierce sealing layer 764 and activate insertion assembly 118.

[0157] **FIG. 10A** illustrates another applicator 1000 for applying on-skin assembly 102 to skin of a host including a removable cap 1012 configured as a sealing element, in accordance with some embodiments. **FIG. 10B** is a partially exploded view of applicator 1000 of **FIG. 10A**. Discussion of applicator 1000 will now take place with reference to both **FIGs. 10A** and **10B**. Applicator 1000 is substantially the same as applicator 700 of **FIGs. 7A** and **7B**, except as described below. Applicator 1000 comprises a housing 1004, which may function substantially the same as housing 704. Applicator 1000 further comprises a telescoping cap 1050 that functions as an actuation member. Applicator 1000 may not include second layer 124 or frangible safety member 766 of FIGs. 7A and 7B. Instead, applicator 1000 may include a removable cap 1012 configured to couple with a distal portion of telescoping cap 1050 actuation member via threads 1014. In some embodiments, a layer 1052 permeable to a sterilizing gas, e.g., Tyvek®, may be included under removable cap 1012 or alternatively attached to removable cap 1012 such that layer 1052 is removed with removable cap 1012. Threads 1014 disposed on removable cap 1012 may be configured to mate with threads (not shown) disposed on an inside surface of the cap forming actuation member 1050. Removable cap 1012 may be detached from actuation member 1050 by twisting removable cap 1012 with respect to telescoping cap 1050, or vice versa. Since telescoping cap actuation member1050 is thus coupled to removable cap 1012, applicator 1000 cannot be activated while removable cap 1012 is secured to applicator 1000. Accordingly, removable cap 1012 provides not only a sealing element configured to provide a sterile barrier and a vapor barrier between an internal and external environment of housing 1004, but also at least premature deployment prevention and drop protection features.

Embodiments Including a Flexible Shell

[0158] Some embodiments can include a flexible member configured as a shell or cover, which is disposed over the housing and operatively coupled to the actuation member. For example, **FIG. 11A** illustrates another applicator 1100 for applying on-skin assembly 102 to skin of a host including a flexible member 1160 disposed over at least a portion of a housing 1104, in accordance with some embodiments. Although not shown, applicator 1100 may further include insertion assembly 118 and on-skin assembly 102 as described in connection with at least **FIGs. 1A-1C**. Applicator 1100 comprises housing 1104, which may encapsulate insertion assembly 118 and on-skin assembly 102. Applicator 1100 may further comprise an actuation

member 1150 disposed on a side of housing 1104 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. Applicator 1100 may further comprise flexible member 1160 disposed over housing 1104. Applicator 1100 may further comprise second layer 124, which may seal a distal portion of flexible member 1160. Thus, second layer 124 in conjunction with flexible member 1160 provide a sealing element configured to provide a sterile barrier and a vapor barrier between an internal and external environment of housing 1104. As shown in FIG. 11A, flexible member 1160 may comprise a flexible section 1162 configured to be disposed over actuation member 1150 such that when flexible section 1162 is pressed, actuation member 1150 is activated. In some embodiments, flexible section 1162 may be bistable in that it has two states: a first, loaded state and a second, deployed state. In such embodiments, flexible section 1162 may provide a positive visual tamper indication when in the second, deployed state. Moreover, the flexible nature of flexible member 1160 may additionally provide premature deployment prevention and drop protection features by absorbing energy that might otherwise provide a physical shock to applicator 1100.

[0159] **FIG. 11B** is a zoomed view of a portion of flexible member 1160 of **FIG. 11A** disposed over actuation member 1150. FIG. 11B merely shows flexible section 1162 of flexible member 1160 in greater detail.

[0160] **FIG. 12A** illustrates another applicator 1200 for applying on-skin assembly 102 to skin of a host including a flexible member 1260 having a bistable configuration that provides a visual indication of deployment, in accordance with some embodiments. **FIG. 12B** is a zoomed view of a portion of the bistable configuration of flexible member 1200 of **FIG. 12A**. Applicator 1200 is substantially the same as applicator 1100 of **FIGs. 11A** and **11B**, except the actuation member (not shown) is disposed on a proximal portion of the housing (not shown) and flexible member 1260 comprises a molded accordion-like section 1262 disposed on a proximal portion of flexible member 1260 and configured to be disposed over the actuation member such that when molded accordion-like section 1262 is pressed, the top-mounted actuation member is activated. **FIG. 12A** illustrates molded accordion-like section 1262 in the first, loaded state, while **FIG. 12B** illustrates molded accordion-like section 1262 in the second, deployed state.

[0161] **FIG. 13A** is an exploded view of another applicator 1300 for applying on-skin assembly 102 to skin of a host including a flexible member 1360 comprising a frangible member

1364 configured to cover an actuation member 1350, in accordance with some embodiments. Applicator 1300 is substantially the same as applicator 1100 of **FIGs. 11A** and **11B**, except as described below. Applicator 1300 comprises housing 1104 of **FIGs. 11A** and **11B,** which comprises actuation member 1150 disposed on a side of housing 1104. Applicator 1300 further comprises a flexible member 1360, which itself comprises a frangible member 1364 and a frangible tab 1366. Applicator 1300 further comprises second layer 124 and, in some embodiments, first layer 122, disposed over a distal opening in flexible member 1360. In this way, flexible member 1360, second layer 124, and in embodiments including it, first layer 122, may form a sealing element configured to provide a sterile barrier and a vapor barrier between and internal environment and an external environment of housing 1304. By pulling down on frangible tab 1366 and then pulling around applicator 1300, frangible tab 1366 and frangible member 1360 may be removed in preparation of using applicator 1300. Thus, at least frangible member 1360 and frangible tab 1366 may simultaneously provide joint sterilization and moisture seals, tamper indication, as well as premature deployment prevention and drop protection features.

[0162] **FIG. 13B** is a condensed view of applicator 1300 of **FIG 13A** before removal of frangible member 1360 and frangible tab 1366. **FIG. 13C** illustrates applicator 1300 of **FIG. 13A** and **13B** having the frangible member 1364 removed, thereby exposing actuation member 1350.

[0163] **FIG. 14** illustrates another applicator 1400 for applying on-skin assembly 102 to skin of a host including a main portion 1460 disposed over at least a portion of applicator 1400 and comprising a flexible material, in accordance with some embodiments. Applicator 1400 comprises a housing 1404 configured to house insertion assembly 118 (not shown) and comprising an aperture 106 (not shown) through which on-skin assembly 102 (not shown) can pass. Applicator 1400 further comprises an actuation member 1470 configured to, upon activation, cause the insertion assembly to insert at least the portion of on-skin assembly 102 into the skin of the host. Main portion 1460 may comprise, for example, rubber, silicone, or any other flexible, soft material that provides shock protection as well as grip to a user. Main portion 1460 may additionally cover actuation member 1470, thereby providing some measure of accidental activation protection, as well as providing additional sealing for applicator 1400. Main portion 1460 may extend over at least a proximal portion of housing 1404, thereby providing both a grip

for the host as well as drop protection. Main portion 1460 may comprise an elastomeric material configured to absorb at least a portion of energy imparted to applicator 1400 when dropped. Furthermore, in other embodiments, main portion 1464 may be removed by pulling a flexible tab 1466 away from applicator 1400 to reveal a hidden button. In such embodiments, main portion 1464 can provide additional tamper indication or button activation prevention features.

Additional Embodiments

[0164] Alternatively or in addition to a removable cap, various embodiments can include one or more other features configured to provide a sterilization seal and/or moisture barrier. A subset of such embodiments may comprise a single housing without a top or bottom cap. For example, **FIG. 15A** illustrates a perspective view of an applicator 1500 for applying on-skin assembly 102 to skin of a host including a peelable layer 1524 configured to seal a distal opening 106 in a housing 1504 and to further seal an actuation member 1550, in accordance with some embodiments. Applicator 1500 comprises housing 1504 configured to house insertion assembly 118 and comprises aperture 106 through which on-skin assembly 102 can pass. Applicator 1500 further comprises actuation member 1550 disposed on a side of housing 1504 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. In some embodiments, peelable layer 1524 is coupled to at least a portion of housing 1524. For example, as shown in at least **FIG. 15A** peelable layer 1524 is configured to seal aperture 106 and actuation member 1550. Thus, peelable layer 1524 forms a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 1504. In some embodiments, peelable layer 1524 is a single piece forming the sealing element. Applicator 1500 may be readied for use by removing peelable layer 1524, thereby exposing both aperture 106 and actuation member 1550. In this way, peelable layer 1524 may also simultaneously provide a tamper indication, premature deployment prevention and drop protection features. **FIG. 15B** illustrates applicator 1500 of FIG. 15A having peelable layer 1524 removed.

[0165] **FIG. 16A** illustrates another applicator 1600 for applying on-skin assembly 102 to skin of a host including a peelable layer 1624 configured to seal a distal aperture 106 in a housing 1604, to further seal an actuation member 1650, and to further seal a vent 1662 permeable to a sterilizing gas, in accordance with some embodiments. **FIG. 16B** is a partially

exploded view of applicator 1600 of **FIG. 16A**. Applicator 1600 comprises a housing 1604 configured to house an insertion assembly, such as insertion assembly 118 shown in **FIG. 8B**, and comprises an aperture 106 through which an on-skin assembly, such as on-skin assembly 102 shown in **FIG. 1B**, can pass. Applicator 1600 further comprises actuation member 1650 disposed on a side of housing 1604 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. Applicator 1600 further comprises vent 1662 configured to be permeable to a sterilizing gas. In some embodiments, a porous polymeric component (e.g., a Porex® plug) may be inserted into vent 1662. In some embodiments, vent 1662 may be disposed on a side of housing 1604, for example, in some embodiments, facing substantially radially outward and substantially perpendicular to aperture 106. In some embodiments, peelable layer 1624 is coupled to at least a portion of housing 1624. For example, as shown in at least **FIG. 16A** peelable layer 1624 is configured to seal aperture 106, actuation member 1650, and vent 1662, e.g., alone two faces of the applicator, one of which comprises vent 1662. Thus, peelable layer 1624 forms a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 1604. For example, peelable layer 1624 may be adhered to housing 1604 thereby sealing aperture 106 on a distal face of housing 1604 but not yet sealing vent 1662. Applicator 1600 may then be subjected to a sterilizing gas, which may permeate still-exposed vent 1662, thereby sterilizing the inside of housing 1604. Peelable layer 1624 may then be disposed over vent 1662 on a second face of housing 1604, thereby sealing vent 1662 and providing a moisture barrier. Applicator 1600 may be readied for use by removing peelable layer 1624, thereby exposing both aperture 106 and actuation member 1650. In this way, peelable layer 1624 may also simultaneously provide a tamper indication, premature deployment prevention and drop protection features.

[0166] **FIG. 17A** illustrates a perspective view of an applicator 1700 for applying on-skin assembly 102 to skin of a host including a peelable layer 1724 configured to seal a distal aperture 106 in a housing 1704 and a inset plug or cap 1770 configured to seal an actuation member 1750, in accordance with some embodiments. Applicator 1700 comprises housing 1704 configured to house insertion assembly 118 and comprises an aperture 106 through which on-skin assembly 102 can pass. Applicator 1700 further comprises actuation member 1750 (see **FIGs. 17B** and **17C**) disposed on a side of housing 1704 and configured to, upon activation,

cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. Applicator 1700 further comprises peelable layer 1724 coupled to at least a portion of housing 1724. For example, as shown in at least **FIG. 17A** peelable layer 1724 is configured to seal aperture 106. Applicator 1700 further comprises inset plug 1770 configured to seal around actuation member 1750. Thus, peelable layer 1724 and inset plug 1770 form a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 1704. As will be described in more detail in connection with **FIGs. 17B** and **17C**, applicator 1700 may be readied for use by removing peelable layer 1724 and inset plug 1770, thereby exposing aperture 106 and actuation member 1750, respectively. In this way, peelable layer 1724 and/or inset plug 1770 may simultaneously provide at least tamper indication and premature deployment prevention features.

[0167] **FIG. 17B** illustrates applicator 1700 of **FIG. 17A** with inset plug 1770 removed. As shown, once inset plug 1770 is removed actuation member 1750 is exposed and readied for activation.

[0168] **FIG. 17C** illustrates the applicator of **FIG. 17B** with peelable layer 1724 further at least partially removed. As shown, once peelable layer 1724 is removed aperture 106 is exposed and applicator 1700 is readied for use by a host.

Additional Removable Cap Embodiments

[0169] **FIG. 18A** illustrates a perspective view of an applicator 1800 for applying on-skin assembly 102 to skin of a host including a removable cap 1812 configured to seal an actuation member and a peelable layer configured to seal a distal opening in a housing, in accordance with some embodiments. **FIG. 18B** is a partially exploded view of applicator 1800 of **FIG. 18A**. Applicator 1800 comprises a housing 1804 configured to house insertion assembly 118 (not shown) and comprising aperture 106 through which on-skin assembly 102 can pass. Applicator 1800 further comprises actuation member 1850 disposed on a proximal (i.e., top) of housing 1804 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. In some embodiments actuation member 1850 protrudes from the proximal portion of housing 1804. Applicator 1800 may further comprises vent 1862 configured to be permeable to a sterilizing gas. In some embodiments, a porous polymeric component (e.g., a Porex® plug) may be inserted into vent 1862. In some

embodiments, vent 1862 may be disposed on a distal portion of housing 1804, for example, adjacent to aperture 106, and may face in substantially the same distal direction as aperture 106. Applicator 1800 further comprises peelable layer 1824 coupled to at least a portion of housing 1804. For example, as shown in at least **FIG. 18A** peelable layer 1824 is configured to seal aperture 106 and vent 1862 along a single planar surface (i.e., a distal surface of housing 1804). Thus, peelable layer 1824 forms a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 1804.

[0170] Applicator 1800 further comprises removable cap 1812 configured to couple with a proximal (i.e., top) portion of housing 1804. In some embodiments, removable cap 1812 further comprises one or more ridges or recesses 1842 configured to provide a tactile indication of grip to the host. In some embodiments, removable cap 1812 is configured to couple with housing 1804 via threads. For example, threads 1814 disposed on removable cap 1812 may be configured to mate with threads 1808 disposed on housing 1804. In some embodiments, applicator 1804 may further comprise a tamper-evident twist-off collar 1830, disposed at a mating location between housing 1804 and removable cap 1812. As previously described in connection with **FIGs. 5A** and **5B**, a first portion 1830a of tamper-evident twist-off collar 1830 may be coupled to removable cap 1812 and a second portion 1830b of tamper-evident twist-off collar 1830 may be coupled to housing 1804. Removable cap 1812 may be detached from housing 1804 by twisting removable cap 1812 with respect to housing 1804, or vice versa, until first portion 1830a breaks free of second portion 1830b, and threads 1808 and 1814 are no longer mated and then pulling removable cap 1812 and housing 1804 apart. In its integral state, removable cap 1812 may provide a seal (e.g., a sterile barrier and a moisture or water vapor barrier) with housing 1804. In its separated state, tamper-evident twist-off collar 1830 may provide an indication of tampering to a user. Accordingly, peelable layer 1824, tamper-evident twist-off collar 1830, and removable cap 1812 may form a sealing element.

[0171] **FIG. 19A** illustrates a perspective view of an applicator 1900 for applying on-skin assembly 102 to skin of a host including a frangible cap 1912 configured to seal an actuation member 1950 and a peelable layer 1924 configured to seal a distal aperture 106 in a housing 1904, in accordance with some embodiments. **FIG. 19B** is a partially exploded view of applicator 1900 of **FIG. 19A**. Applicator 1900 may comprise substantially the same components as applicator 1800 of FIGs. 18A and 18B, however, omitting tamper-evident twist-off collar

1830, threads 1808 and 1814, and replacing removable cap 1812 with frangible cap 1912 and pull tab 1966. For example, housing 1904, aperture 106, vent 1962, actuation member 1950 and peelable layer 1924 correspond with housing 1804, aperture 106, vent 1862, actuation member 1850 and peelable layer 1824, respectively. Furthermore, applicator 1900 may further include a protrusion 1920 configured to inhibit applicator 1900 from rolling, as previously described in connection with FIG. 2.

[0172] Frangible cap 1912 is configured to couple with a proximal portion of housing 1904. In some embodiments, frangible cap 1912 comprises pull tab 1966. Frangible cap 1912 is configured to be removed by pulling on pull tab 1966, thereby releasing frangible cap 1912. In this way, frangible cap 1912, and peelable layer 1924 may form a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal environment and an external environment of housing 1904. Frangible cap 1912 further provides a tamper indicator for a host using applicator 1900 such that if frangible cap 1912 is broken, tampering would be visually evident to a user. Frangible cap 1912 additionally provides premature deployment prevention and drop protection features in that, until removed, it prevents access to actuation member 1950.

Embodiments Including Multiple Peelable Layers

[0173] Some embodiments can include one or more peelable layers (e.g., sheets of material which are coupled (e.g. adhesively, heat staking) to a portion of the applicator and easily removable from the housing by a peeling action) which is coupled to, or integrally formed with, a removable cap. **FIG. 20A** illustrates a perspective view of an applicator 2000 for applying on-skin assembly 102 to skin of a host including a first peelable layer 2024 configured to seal a distal aperture 106 in a housing 2004 and a second peelable layer 2064 configured to seal an actuation member 2050 disposed in a proximal opening in the housing, in accordance with some embodiments. **FIG. 20B** illustrates the actuation member of the applicator of **FIG. 20A** in each of a pre-activated position and an activated position. Applicator 2000 comprises a housing 2004 configured to house insertion assembly 118 (not shown) and comprising aperture 106 (not shown) through which on-skin assembly 102 can pass. Applicator 2000 further comprises actuation member 2050 disposed on a proximal (i.e., top) of housing 2004 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. In some embodiments actuation member 2050 is recessed into the proximal

portion of housing 2004. Applicator 200 further comprise first peelable layer 2024 is configured to seal aperture 106 in housing 2004 and second peelable layer 2064 configured to seal actuation member 2050. Accordingly, first peelable layer 2024 and second peelable layer 2064 may form a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 2004. Applicator 2000 may be readied for use by removing first peelable layer 2024 and second peelable layer 2064. Accordingly, first peelable layer 2024 and second peelable layer 2064 may simultaneously provide a tamper indication and premature deployment prevention feature.

[0174] **FIG. 21A** illustrates another applicator 2100 for applying on-skin assembly 102 to skin of a host including a inset plug 2170 configured to seal an actuation member 2150 and a peelable layer 2124 configured to seal a distal aperture 106 in a housing 2104, in accordance with some embodiments. Applicator 2100 comprises housing 2104 configured to house insertion assembly 118 and comprises an aperture 106 through which on-skin assembly 102 can pass. Applicator 2100 further comprises actuation member 2150 (see **FIG. 21C**) disposed on a proximal (i.e., top) portion of housing 2104 and configured to, upon activation, cause insertion assembly 118 to insert at least a portion of on-skin assembly into the skin of a host. In some embodiments, actuation member 2150 is recessed into the proximal portion of housing 2104. Applicator 2100 further comprises peelable layer 2124 coupled to at least a portion of housing 2104. For example, peelable layer 2124 is configured to seal aperture 106 (see **FIG. 21B**). Applicator 2100 further comprises inset plug 2170 configured to seal actuation member 2150. Thus, peelable layer 2124 and inset plug 2170 form a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal and external environment of housing 2104. Applicator 2100 may further comprise one or more ridges or recesses 2144 configured to provide a tactile indication of grip to the host. In some embodiments, applicator 2100 may further comprise comprises at least one protrusion 2120 configured to inhibit rolling of applicator 2100. Protrusion 2120 may also function as an orientation indicator for the user.

[0175] In an alternate embodiment, housing 2104 may be a deformable container capable of flexing inwards and outwards. In such embodiments, a squeezing of housing 2104 may activate an insertion assembly within housing 2104, such as insertion assembly 118 (shown in **FIG. 8B**). The deformation caused by the squeezing of housing 2104 may decouple a trigger arm or latch (not shown) which can release the insertion assembly. Furthermore, in such

embodiments, ridges or recesses 2144 may be activation indicators to notify the user where to squeeze in order to activate and fire the insertion assembly.

[0176] As shown more detail by **FIGs. 21B** and **21C**, applicator 2100 may be readied for use by removing peelable layer 2124 and inset cap 2170, thereby exposing aperture 106 and actuation member 2150, respectively. In this way, peelable layer 2124 and/or inset plug 2170 may simultaneously provide at least tamper indication and premature deployment prevention features.

[0177] **FIG. 21B** illustrates applicator 2100 of **FIG. 21A** having peelable layer 2124 removed. As shown, once peelable layer 2124 is removed aperture 106 is exposed.

[0178] **FIG. 21C** illustrates applicator 2100 of **FIG. 21A** having inset cap 2170 removed. As shown, once inset cap 2170 is removed actuation member 2150 is exposed and readied for activation.

[0179] **FIG. 22A** illustrates a perspective view of an applicator 2200 for applying on-skin assembly 102 to skin of a host including a first peelable layer 2224 configured to seal a distal aperture 106 in a housing 2204 and to seal a vent 2262 (optional) permeable to a sterilizing gas and a second peelable layer 2264 configured to seal an actuation member (not shown) disposed in a proximal opening in housing 2204, in accordance with some embodiments. **FIG. 22B** is a partially exploded view of applicator 2200 of **FIG. 22A**. Applicator 2200 may be substantially the same as applicator 2000 of **FIGs. 20A** and **20B**, except as described below. Applicator 2200 comprises housing 2204, first peelable layer 2224, actuation member (not shown), and second peelable layer 2264, which correspond to housing 2004, first peelable layer 2024, actuation member (not shown), and second peelable layer 2064 of applicator 2000, respectively. Applicator 2200 further comprises vent 2262, which may correspond substantially to vent 1962 as previously described in connection with of **FIGs. 19A** and **19B**. Accordingly, first peelable layer 1924 is configured to seal both aperture 106 of housing 2204 and vent 2262. Of note, vent 2262 being disposed on a distal portion of housing 2204 adjacent to aperture 106 may additionally provide at least one protrusion 2220 configured to inhibit rolling of applicator 2200. Protrusion 2220 may also function as an orientation indicator for the user.

Embodiments Utilizing Protective Cups

[0180] **FIG. 23** illustrates a collapsible cup 2390 having a removable lid 2392 and configured to enclose an applicator 2300 for applying on-skin assembly 102 to skin of a host configured to fit within, in accordance with some embodiments. **C**ollapsible cup 2390 has a removable and/or peelable lid 2392. Collapsible cup 2390 is configured to act as a sealing element that seals applicator 2300 from an environment outside collapsible cup 2390. In some embodiments, collapsible cup 2390 comprises an elastomer. In some embodiments, collapsible cup 2390 is configured to collapse after removal of removable and/or peelable lid 2392. Applicator 2300 may correspond to any applicator, including any described in this detailed description.

[0181] **FIG. 24A** illustrates a cup 2490 having a removable lid 2492 and configured to enclose an applicator 2400 for applying on-skin assembly 102 to skin of a host, in accordance with some embodiments. In some embodiments, cup 2390 is in injection molded cup. Cup 2490 is configured to act as a sealing element that seals applicator 2400 from an environment outside cup 2490. Applicator 2400 (see **FIG. 24B**) may be readied for use by peeling removable lid 2492 from cup 2390 and removing applicator 2400 therefrom. Applicator 2400 may be substituted with any previously described applicator.

[0182] **FIG. 24B** is a cutaway view of cup 2490 and applicator 2400 of **FIG. 24A**. As shown, within cup 2490 is disposed applicator 2400. In some embodiments, cup 2490 may further comprise an on-skin assembly alignment feature 2494. In some embodiments, on-skin alignment feature 2494 may further comprise a needle protection feature in that, by restraining at least lateral movement of the needle of insertion assembly 118, on-skin assembly alignment feature 2494 not only protects the needle from damage or outside contact, it also keeps on-skin assembly 102 in proper alignment.

Actuation member Alternatives

[0183] The present application sets forth a plurality of different applicator embodiments. However, the present application is not limited solely to the isolated embodiments, described. For example, any actuation member of any describe embodiment may be replaced with any other actuation member previously described, as desired. Any actuation member may be used to activate an insertion assembly, such as insertion assembly 118 (not shown). For example, any applicator may alternatively comprise an actuation member disposed on a side of the housing

(see **FIGs. 1A-6B, 11A, 11B, 13A-17C** and **25**), an actuation member disposed on a proximal (i.e., top) portion of the housing (see **FIGs. 12A, 12B,** and **18A-22B**), an actuation member that is a cap in and of itself (see **FIGs. 7A-10B**), an actuation member that arms via depression and activates via pressing of a flexure (see **FIG. 9**), a common push button, a bistable button (see **FIGs. 11A-12B**), or any of the above example, however, further permeable to a sterilizing gas (see **FIGs. 25A-25B**). In some embodiments, any applicator may comprise a plurality of actuation members, in which depression of one or more of the plurality of actuation members may activate an insertion assembly. In some embodiments, depression of at least two actuation members, simultaneously or in sequence, may be required to activate an insertion assembly.

[0184] **FIG. 25A** is a cutaway view of an applicator 2500 for applying on-skin assembly 102 to skin of a host including an actuation member 2550 that is permeable to a sterilizing gas, in accordance with some embodiments. **FIG. 25B** is a zoomed view of the actuation member of **FIG. 25A**. Applicator 2500 comprises an actuation member 2550, which itself comprises a material that is permeable to a sterilizing gas, for example, Porex®. The structure of applicator 2500 is not of importance here and, thus, applicator 2500 may correspond to any applicator, including any described herein. Thus, any applicator described herein may have its actuation member replaced with actuation member 2550, e.g., replaced with an actuation member that is permeable to a sterilizing gas. In such embodiments, any vent may be omitted as the actuation member may also function as the vent.

Bulk Manufacturing, Sterilizing, and/or Sealing of Applicators

[0185] As previously stated, it may be desirable to be able to manufacture, sterilize and/or seal applicators in bulk. This would not only reduce the per-unit cost of manufacture, it would potentially decrease the cost to consumers of the applicators. Accordingly, below are described a few embodiments that may allow for bulk manufacturing, sterilizing and/or sealing of multiple applicators simultaneously.

[0186] **FIG. 26A** is a cutaway view of a soluble moisture barrier 2624 having a plurality of perforations 2628 for an applicator 2600 for applying on-skin assembly 102 to skin of a host, in accordance with some embodiments. For example, soluble moisture barrier 2624 having one or more perforations 2628 may be utilized as a sealing element and may be disposed over an opening 2626 in a removable cap 2612, for example, as previously described in connection with

at least **FIGs. 1A-1C** and **3A-3C**. The applicator 2600 may be subjected to a sterilizing gas, which may ingress and then egress through one or more perforations 2628, thereby sterilizing the components within applicator 2600. Once sterilization is complete, soluble moisture barrier 2624 may be subjected to a temperature sufficient to at least partially dissolve or reflow moisture barrier material 2624 which can seal perforations 2628, as shown in **FIG. 26B**. Thus, in one state, soluble moisture barrier 2624 acts as a vent to allow for sterilization of applicator 2600, and in another state, soluble moisture barrier 2624 acts as a seal for applicator 2600.

[0187] **FIG. 26B** is a cutaway view of soluble moisture barrier 2624 of **FIG. 26A** after heating such that soluble moisture barrier 2624 has cooled down and solidified. Soluble moisture barrier 2624 is configured to redistribute itself in a form in which plurality of perforations 2628 are closed and sealed. Because the operative transforming method is application of heat sufficient to melt soluble moisture barrier material 2624, bulk sterilization and moisture sealing of a plurality of applicators may be achieved without direct contact with components.

[0188] **FIG. 27A** is a cutaway view of a moisture barrier 2724 including an elastomeric layer 2724b and a perforated layer 2724a, in accordance with some embodiments. Moisture barrier 2724 may be utilized as a sealing element and may be integral to a removable cap 2712, for example, as previously described in connection with any previous figure illustrating a removable cap. Perforated layer 2724a may be considered a first portion of a sealing element and may comprise a plurality of perforations 2728 and an adhesive layer 2746 disposed on a first side of perforated layer 2724a. Elastomeric layer 2724b may be considered a second portion of the sealing element and may comprise a portion permeable to a sterilizing gas. Elastomeric layer 2724b is disposed adjacent to the first side of perforated layer 2724a. Elastomeric layer 2724b is configurable in a first configuration where elastomeric layer 2724b is spatially separated from perforated layer 2724a, providing a pathway for a sterilizing pass to pass through the plurality of perforations 2729 and the portion of elastomeric layer 2724a permeable to the sterilizing gas. Elastomeric layer 2724b may transition to a second configuration where elastomeric layer 2724b is adhered to perforated layer 2724a via adhesive layer 2746, removing the pathway for the sterilizing gas and causing moisture barrier 2724 to be impermeable to the sterilizing gas. In some other embodiments, adhesive layer 2746 may not be included, and elastomeric layer 2724b

may be drawn against perforated layer 2724a without the need for adherence, thereby sealing the applicator. **FIG. 27A** illustrates the first configuration.

[0189] As shown in **FIG. 27A**, applicator 2700 may be subjected to a sterilizing gas, which may ingress and then egress through plurality of perforations 2728 in perforated layer 2724a and through a transmissive layer 2730 (e.g., Tyvek®) permeable to the sterilizing gas, thereby sterilizing the components within applicator 2700. Once sterilization is complete, applicator 2700 may be subjected to a partial vacuum, thereby creating a pressure gradient sufficient to transition elastomeric layer 2724b from the first configuration to the second configuration. Due to the pressure gradient, elastomeric layer 2724b is drawn against perforated layer 2427a which seals moisture barrier 2724 from sterilizing gas and moisture, as shown in **FIG. 27B**. Generically, this concept covers any design that utilizes pressure gradient to actuate a valve that can be closed after gaseous sterilization (e.g. Ethylene Oxide sterilization). For example, another embodiment may include an elastomeric stopper that is configured to move to close air/vapor passage when a vacuum of a sufficient flow rate is applied.

[0190] **FIG. 27B** is a cutaway view of moisture barrier 2724 of **FIG. 27A** illustrating elastomeric layer 2724b and perforated layer 2724a in the second orientation such that the moisture barrier is impermeable to the sterilizing gas and to moisture, in accordance with some embodiments. Because the operative transforming method is the application of a partial vacuum sufficient to actuate elastomeric layer 2724b from the first configuration to the second configuration, batch sterilization and/or vapor (e.g. water vapor) sealing of a plurality of applicators may be achieved simultaneously by subjecting a plurality of applicators to the partial vacuum simultaneously. This may aid in high efficiency sterilization of a plurality of applicators.

[0191] **FIG. 28A** illustrates a tray 2802 configured to hold a plurality of applicators 2800 for bulk sterilization and moisture barrier sealing, in accordance with some embodiments. The plurality of applicators 2800 may each, for example, have a structure similar to that described in connection with FIG. 27A and 27B except wherein elastomeric layer 2724b is disposed on an outside of perforated layer 2724a. In such embodiments, elastomeric layer 2724b would be in the first configuration as previously described. The plurality of applicators 2800 may be disposed on tray 2802.

[0192] As shown in **FIG. 28A**, applicators 2800 may be subjected to a sterilizing gas, which may ingress and then egress through plurality of perforations 2728 in perforated layer 2724a and through the transmissive layer 2730 (e.g., Tyvek®, see **FIGs. 27A-B**) of elastomeric layer 2724b permeable to the sterilizing gas, thereby sterilizing the components within each of the plurality of applicators 2800. Once sterilization is complete, a force applicator 2804 may be applied to the plurality of applicators 2800 subjecting them to a force sufficient to transition elastomeric layer 2824b in each of the plurality of applicators 2800 from the first configuration to the second configuration, thereby rendering moisture barrier 2824 impermeable to the sterilizing gas and to moisture. Such a transition is as shown in **FIG. 28B**.

[0193] **FIG. 28B** is a zoomed view of tray 2802 of **FIG. 28A** illustrating each of the plurality of applicators 2800 in the first configuration, permeable to a sterilizing gas, and the second configuration impermeable to the sterilizing gas and to moisture. Because the operative transforming method is application of a force sufficient to actuate each applicator's elastomeric layer 2724b from the first configuration to the second configuration, batch sterilization and/or vapor sealing of a plurality of applicators may be achieved simultaneously by subjecting a plurality of applicators to the physical force simultaneously via force applicator 2804.

[0194] **FIG. 29** is an exploded view of a sealing element comprising a first layer 2922 permeable to a sterilizing gas and a second layer 2924 impermeable to the sterilizing gas and moisture, in accordance with some embodiments. The sealing element may be integral to a removable cap 2912, for example, as previously described in connection with any previous figure illustrating a removable cap.

[0195] First layer 2922 may comprise Tyvek®, although any other material permeable to a sterilizing gas may be utilized. Application of first layer 2922 to removable cap 2912 may allow for the subsequent ingress and egress of a sterilizing gas during manufacture. Second layer 2924 may comprise a metallic foil, although any other material impermeable to moisture (e.g., water vapor) may be applied, for example, a metallic foil (e.g. aluminum, titanium), a metallic substrate, aluminum oxide coated polymer, parylene, a polymer coated with a metal applied via vapor metallization, silicon dioxide coated polymer, or any material having a moisture vapor transmission rate less than 10 grams/100in^2 or preferably less than 1 grams/100in^2. First layer 2922 and second layer 2924 may seal an opening (not shown) in removable cap 2912. Application of second layer 2924 over first layer 2922 after sterilization may further provide a

moisture barrier for applicator 2900. Because second layer 2924 may be applied simultaneously to a plurality of applicators, batch sterilization and/or vapor sealing may be achieved.

[0196] **FIG. 30A** is a zoomed view of a sealing element comprising a vent 3062 including a material permeable to a sterilizing gas, in accordance with some embodiments. In some embodiments, the material may comprise a porous polymeric component such as Porex®, although any material permeable to a sterilizing gas may be utilized. The sealing element may be integral to a removable cap 3012, for example, as previously described in connection with any previous figure illustrating a removable cap. One or more applicators utilizing the sealing element comprising vent 3062 may be subjected to a sterilizing gas, which may ingress and egress the applicators via vent 3062. Once sterilization is complete, the sealing element comprising vent 3062 may be subjected to a temperature sufficient to form a sintered layer 3063 (see **FIG. 30B**) in the porous polymeric component of vent 3062.

[0197] **FIG. 30B** is a zoomed view of the sealing element of **FIG. 30A** illustrating sintered layer 3063 of vent 3062, which is impermeable to the sterilizing gas. Because the operative transforming method is application of heat sufficient to sinter the porous polymeric component of vent 3062, batch sterilization and/or vapor sealing of a plurality of applicators may be achieved simultaneously.

[0198] In an alternate embodiment, applicators may be enclosed in a container after sterilization is complete. The container may enclose the applicator and function as a moisture barrier. This may aid in batch sterilization and/or vapor sealing of a plurality of applicators. In some embodiments, the container may be a bag, a wrap, a thermoform, or some form of kitted device.

Methods of Manufacturing

[0199] **FIG. 32** is a flowchart 3200 illustrating a method of manufacturing an applicator for applying on-skin assembly 102 to skin of a host, in accordance with some embodiments. Steps in flowchart 3200 may be performed for manufacturing any applicator as previously described in connection with any of the previous figures. Although certain steps are set forth below, a method of manufacturing such an applicator may comprise more, fewer, or different steps, in the same or different order from that set forth below. Moreover, in some embodiments, this method may be utilized to manufacture a plurality of applicators in batches.

[0200] Flowchart 3200 comprises block 3202, which includes providing an insertion assembly configured to insert at least a portion of the on-skin assembly into the skin of the host. For example, on-skin assembly 102 may be provided as previously described in connection with at least **FIG. 1B**.

[0201] Flowchart 3200 further comprises block 3204, which includes providing a housing configured to receive the insertion assembly, the housing comprising an aperture through which the on-skin assembly can pass. Such a housing may be as previously described in connection with any of **FIGs. 1A-30**.

[0202] Flowchart 3200 further comprises block 3206, which includes providing an actuation member configured to, upon activation, actuate the insertion assembly to insert at least the portion of the on-skin assembly into the skin of the host. For example, any actuation member as previously described in connection with any of **FIGs. 1A-30** may be provided.

[0203] Flowchart 3200 further comprises block 3208, which includes providing a sealing element configured to provide a sterile barrier and/or a vapor barrier between an internal environment of the housing and an external environment of the housing. For example, a sealing element as previously described in connection with any of **FIGs. 1A-30** may be provided. For example, such a sealing element may not necessarily comprise a single element but instead may comprise any combination of removable caps, with or without threads, first or second layers, sealing layers, peelable sealing layers, frangible members or caps, flexible members, O-rings, bags, or other seals, as previously described in connection with any combination from **FIGs. 1A-30**.

[0204] **FIG. 33** is a flowchart illustrating another method of manufacturing an applicator for applying on-skin assembly 102 to skin of a host, in accordance with some embodiments. Steps in flowchart 3300 may be performed for manufacturing any applicator as previously described in connection with any of the previous **FIGs.** Although certain steps are set forth below, a method of manufacturing such an applicator may comprise more, fewer, or different steps, in the same or different order from that set forth below. Moreover, in some embodiments, this method may be utilized to manufacture a plurality of applicators in batches.

[0205] Flowchart 3300 comprises block 3302, which includes providing an insertion assembly configured to insert at least a portion of the on-skin assembly into the skin of the host.

For example, on-skin assembly 102 may be provided as previously described in connection with at least **FIG. 1B**.

[0206] Flowchart 3300 further comprises block 3304, which includes providing a housing configured to receive the insertion assembly, the housing comprising an aperture through which the on-skin assembly can pass. Such a housing may be as previously described in connection with any of **FIGs. 1A-30**.

[0207] Flowchart 3300 further comprises block 3306, which includes providing an actuation member configured to, upon activation, actuate the insertion assembly to insert at least the portion of the on-skin assembly into the skin of the host. For example, any actuation member as previously described in connection with any of **FIGs. 1A-30** may be provided.

[0208] Flowchart 3300 further comprises block 3308, which includes exposing at least an internal environment of the housing to a sterilizing gas. For example, an internal environment of any housing as previously described in connection with FIGs. 1A-30 may be exposed to a sterilizing gas, such as ethylene oxide (ETO), as previously described or by exposing an applicator to the sterilizing gas before formation, provision, manufacture or application of a sealing element that transforms the housing from permeable to the sterilizing gas to impermeable to at least the sterilizing gas.

[0209] Flowchart 3300 further comprises block 3310, which includes allowing for egress of the sterilizing gas from the internal environment of the housing. For example, upon exposing the applicator to the sterilizing gas, the sterilizing gas may be removed and a sufficient amount of time may elapse before continuing the manufacturing process to allow for egress of substantially all sterilizing gas from the internal environment of the housing.

[0210] Flowchart 3300 further comprises block 3312, which includes sealing the internal environment of the housing from an external environment of the housing. For example, a sealing element as previously described in connection with any of **FIGs. 1A-30** may be provided. For example, such a sealing element may not necessarily comprise a single element but instead may comprise any combination of removable caps, with or without threads, first or second layers, sealing layers, peelable sealing layers, frangible members or caps, flexible members, O-rings, bags, or other seals, as previously described in connection with any combination from **FIGs. 1A-30**.

[0211] In some embodiments, at least sealing the internal environment of the housing from an external environment of the housing is performed simultaneously for a plurality of applicators. In some embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting the plurality of applicators to a partial vacuum exceeding a threshold such that a sealing element of each of the plurality of applicators transitions from being permeable to the sterilizing gas to being impermeable to the sterilizing gas, as previously described in connection with at least **FIGs. 27A** and **27B**.

[0212] In some other embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting the plurality of applicators to a physical force sufficient to cause a sealing element of each of the plurality of applicators to transition from a first physical configuration permeable to the sterilizing gas to a second physical configuration impermeable to the sterilizing gas, as previously described in connection with **FIGs. 28A** and **28B**.

[0213] In yet other embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting a sealing element, comprising a plurality of perforations, of each the plurality of applicators to a temperature sufficient to at least partially melt each of the sealing elements thereby sealing the plurality of perforations in each of the sealing elements, as previously described in connection with **FIGs. 26A** and **26B**.

[0214] In yet other embodiments, sealing the internal environment of the housing from an external environment of the housing comprises subjecting a sealing element, comprising a porous polymeric component, of each of the plurality of applicators to a temperature sufficient to form a sintered layer in the porous polymeric component of each sealing element, as previously described in connection with **FIGs. 30A** and **30B**.

[0215] In yet other embodiments, sealing the internal environment of the housing from an external environment of the housing comprises depositing a layer impermeable to the sterilizing gas on at least a portion of each of the plurality of applicators, as previously described in connection with **FIG. 29**. In some such embodiments, the layer comprises at least one of a metallic foil (e.g. aluminum, titanium) , a metallic substrate, aluminum oxide coated polymer, parylene, a polymer coated with a metal applied via vapor metallization, silicon dioxide coated polymer, or any material having a moisture vapor transmission rate less than 10 grams/100in^2 or preferably less than 1 grams/100in^2.

[0216] The specification and figures of U.S. Patent App. No. 15/387,088 are provided as an Appendix to this application, entitled "APPENDIX TO DEXCOM.393PR (788.C3.001 DEXCOM 697)", and form a part of this application.

[0217] It should be appreciated that all methods and processes disclosed herein may be used in any glucose monitoring system, continuous or intermittent. It should further be appreciated that the implementation and/or execution of all methods and processes may be performed by any suitable devices or systems, whether local or remote. Further, any combination of devices or systems may be used to implement the present methods and processes.

[0218] The above description presents the best mode contemplated for carrying out the present invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use this invention. This invention is, however, susceptible to modifications and alternate constructions from that discussed above that are fully equivalent. Consequently, this invention is not limited to the particular embodiments disclosed. On the contrary, this invention covers all modifications and alternate constructions coming within the spirit and scope of the invention as generally expressed by the following claims, which particularly point out and distinctly claim the subject matter of the invention. While the disclosure has been illustrated and described in detail in the drawings and foregoing description, such illustration and description are to be considered illustrative or exemplary and not restrictive.

[0219] All references cited herein are incorporated herein by reference in their entirety. To the extent publications and patents or patent applications incorporated by reference contradict the disclosure contained in the specification, the specification is intended to supersede and/or take precedence over any such contradictory material.

[0220] Unless otherwise defined, all terms (including technical and scientific terms) are to be given their ordinary and customary meaning to a person of ordinary skill in the art, and are not to be limited to a special or customized meaning unless expressly so defined herein. It should be noted that the use of particular terminology when describing certain features or aspects of the disclosure should not be taken to imply that the terminology is being re-defined herein to be restricted to include any specific characteristics of the features or aspects of the disclosure with which that terminology is associated. Terms and phrases used in this application, and variations thereof, especially in the appended claims, unless otherwise expressly stated, should

be construed as open ended as opposed to limiting. As examples of the foregoing, the term 'including' should be read to mean 'including, without limitation,' 'including but not limited to,' or the like; the term 'comprising' as used herein is synonymous with 'including,' 'containing,' or 'characterized by,' and is inclusive or open-ended and does not exclude additional, unrecited elements or method steps; the term 'having' should be interpreted as 'having at least;' the term 'includes' should be interpreted as 'includes but is not limited to;' the term 'example' is used to provide exemplary instances of the item in discussion, not an exhaustive or limiting list thereof; adjectives such as 'known', 'normal', 'standard', and terms of similar meaning should not be construed as limiting the item described to a given time period or to an item available as of a given time, but instead should be read to encompass known, normal, or standard technologies that may be available or known now or at any time in the future; and use of terms like 'preferably,' 'preferred,' 'desired,' or 'desirable,' and words of similar meaning should not be understood as implying that certain features are critical, essential, or even important to the structure or function of the invention, but instead as merely intended to highlight alternative or additional features that may or may not be utilized in a particular embodiment of the invention. Likewise, a group of items linked with the conjunction 'and' should not be read as requiring that each and every one of those items be present in the grouping, but rather should be read as 'and/or' unless expressly stated otherwise. Similarly, a group of items linked with the conjunction 'or' should not be read as requiring mutual exclusivity among that group, but rather should be read as 'and/or' unless expressly stated otherwise.

[0221] Where a range of values is provided, it is understood that the upper and lower limit, and each intervening value between the upper and lower limit of the range is encompassed within the embodiments.

[0222] With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity. The indefinite article 'a' or 'an' does not exclude a plurality. A single processor or other unit may fulfill the functions of several items recited in the claims. The mere fact that certain measures are recited in mutually different dependent claims does not indicate that a combination of these measures cannot be used to advantage. Any reference signs in the claims should not be construed as limiting the scope.

[0223] It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases 'at least one' and 'one or more' to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles 'a' or 'an' limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases 'one or more' or 'at least one' and indefinite articles such as 'a' or 'an' (e.g., 'a' and/or 'an' should typically be interpreted to mean 'at least one' or 'one or more'); the same holds true for the use of definite articles used to introduce claim recitations. In addition, even if a specific number of an introduced claim recitation is explicitly recited, those skilled in the art will recognize that such recitation should typically be interpreted to mean at least the recited number (e.g., the bare recitation of 'two recitations,' without other modifiers, typically means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to 'at least one of A, B, and C, etc.' is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., 'a system having at least one of A, B, and C' would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to 'at least one of A, B, or C, etc.' is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., 'a system having at least one of A, B, or C' would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase 'A or B' will be understood to include the possibilities of 'A' or 'B' or 'A and B.'

[0224] All numbers expressing quantities of ingredients, reaction conditions, and so forth used in the specification are to be understood as being modified in all instances by the term

'about.' Accordingly, unless indicated to the contrary, the numerical parameters set forth herein are approximations that may vary depending upon the desired properties sought to be obtained. At the very least, and not as an attempt to limit the application of the doctrine of equivalents to the scope of any claims in any application claiming priority to the present application, each numerical parameter should be construed in light of the number of significant digits and ordinary rounding approaches.

[0225] Furthermore, although the foregoing has been described in some detail by way of illustrations and examples for purposes of clarity and understanding, it is apparent to those skilled in the art that certain changes and modifications may be practiced. Therefore, the description and examples should not be construed as limiting the scope of the invention to the specific embodiments and examples described herein, but rather to also cover all modification and alternatives coming with the true scope and spirit of the invention.

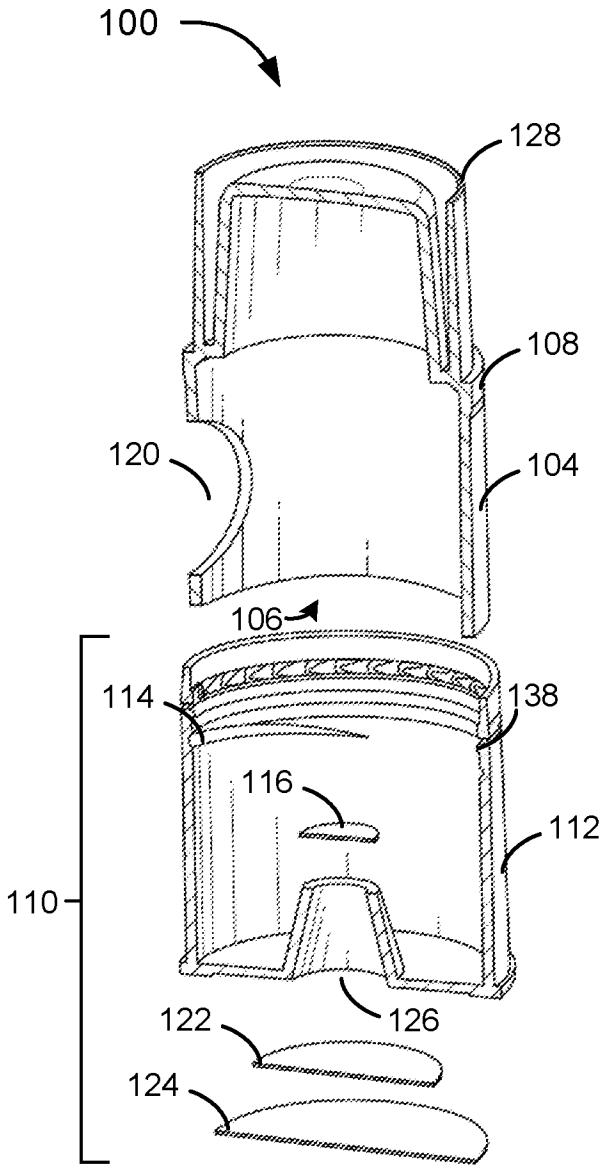


FIG. 1A

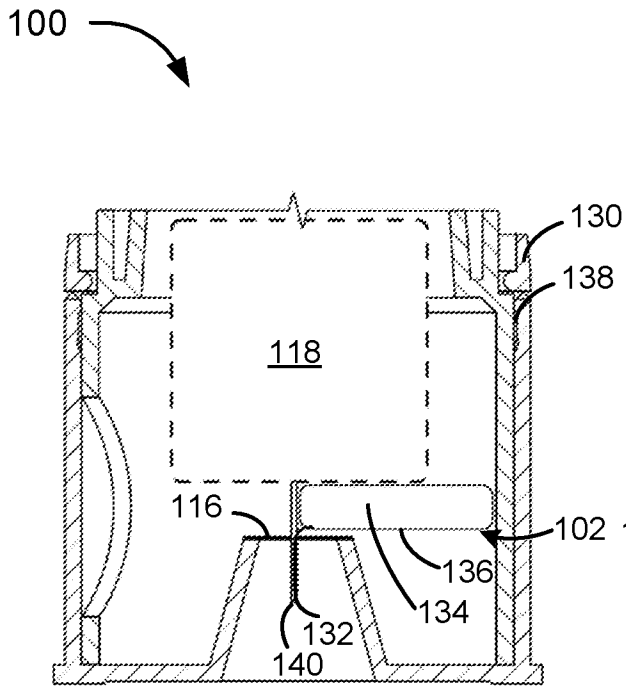


FIG. 1B

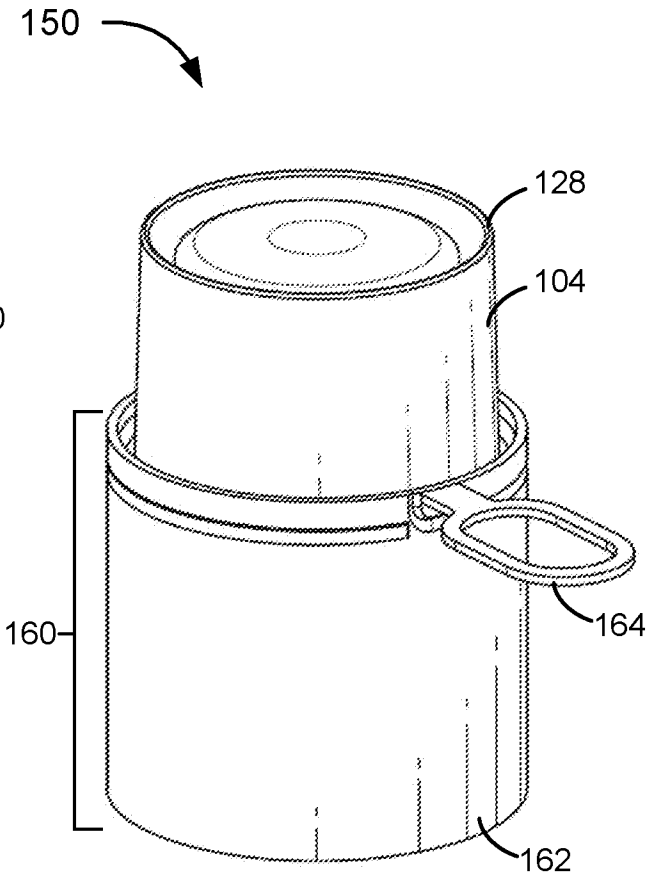


FIG. 1C

APPENDIX TO DEXCOM 394PR (788.C5.001 DEXCOM 683)

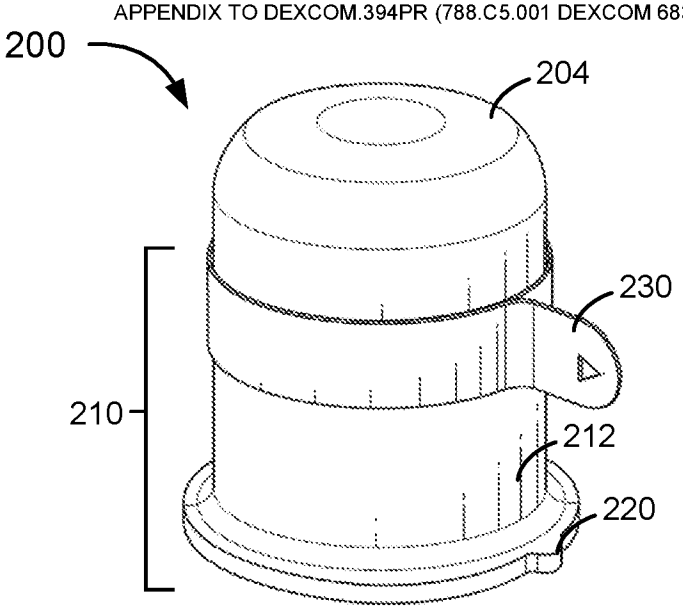


FIG. 2A

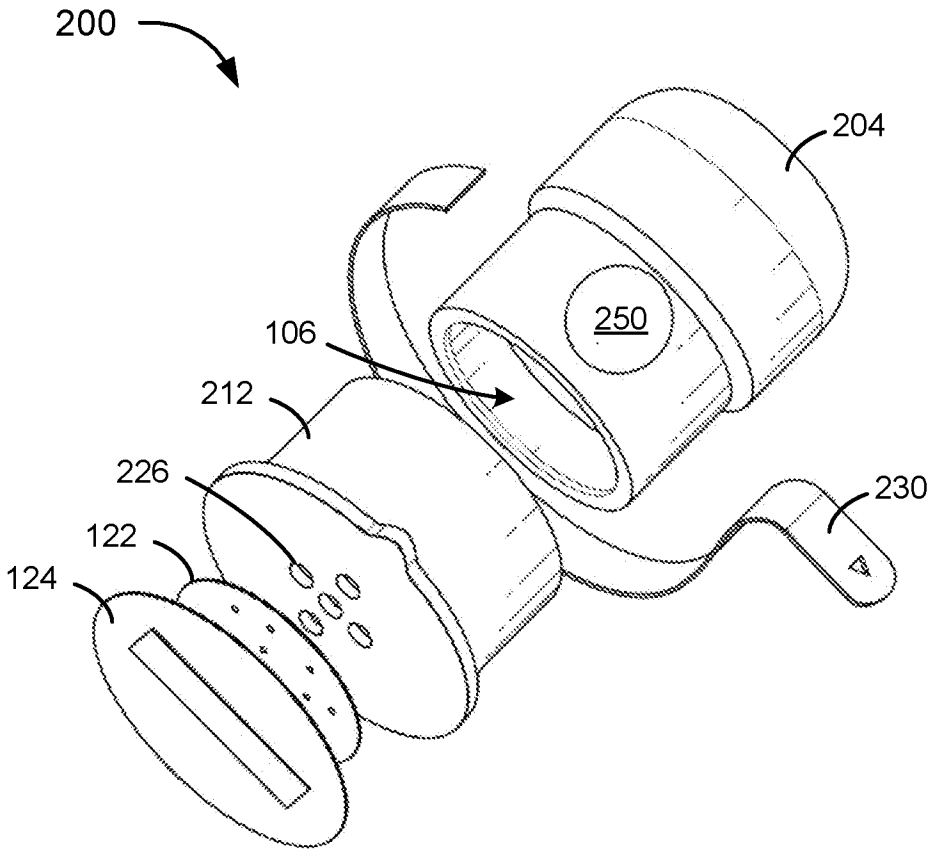


FIG. 2B

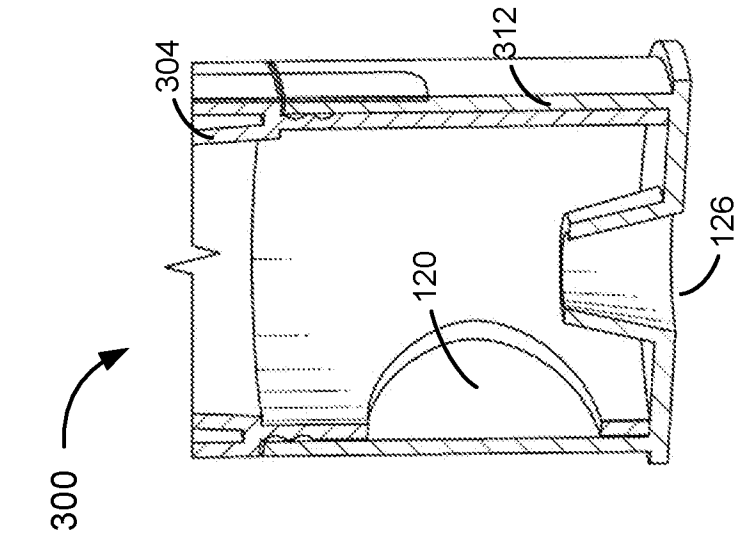


FIG. 3C

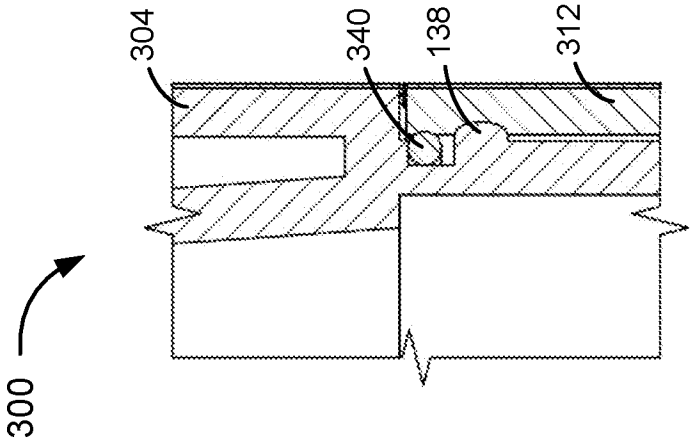


FIG. 3B

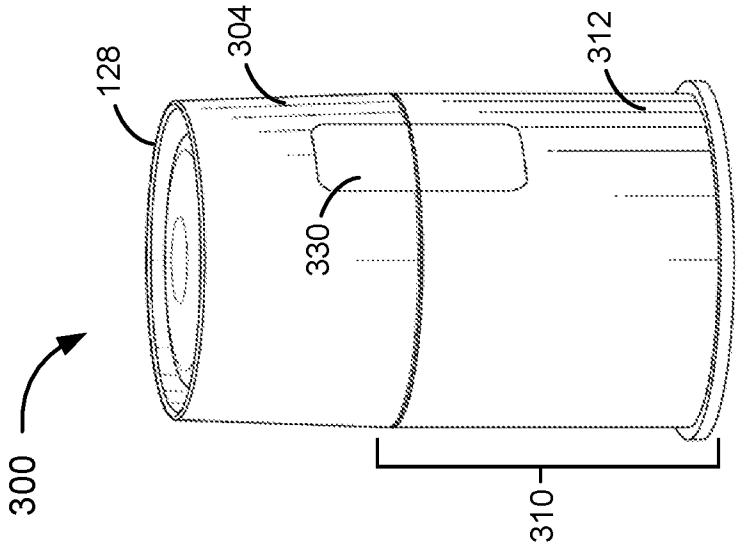


FIG. 3A

788.C3.001

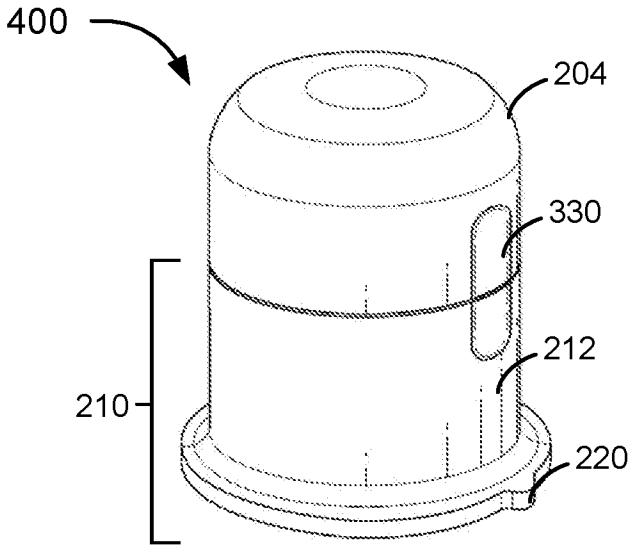


FIG. 4A

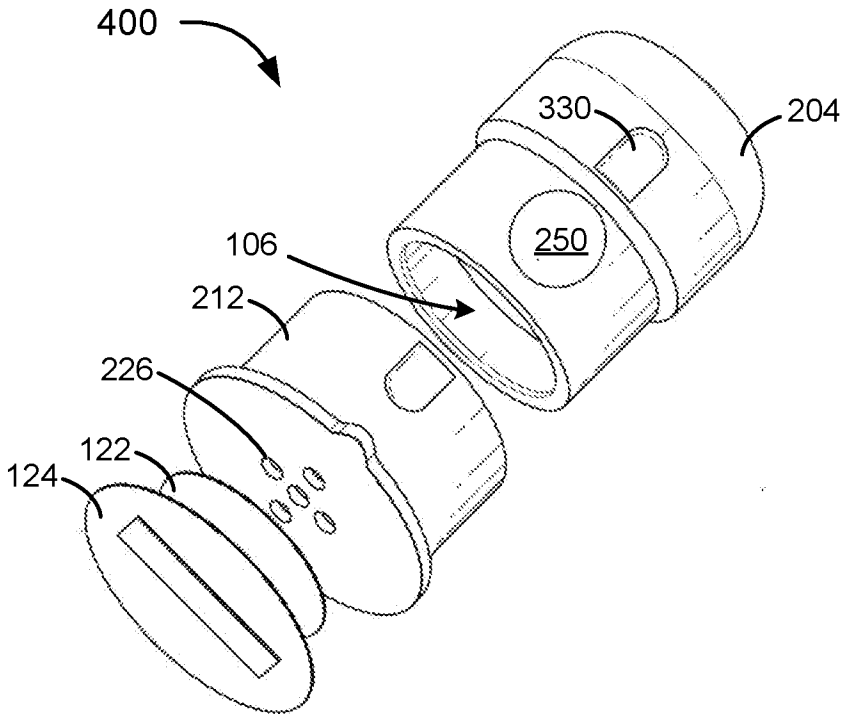


FIG. 4B

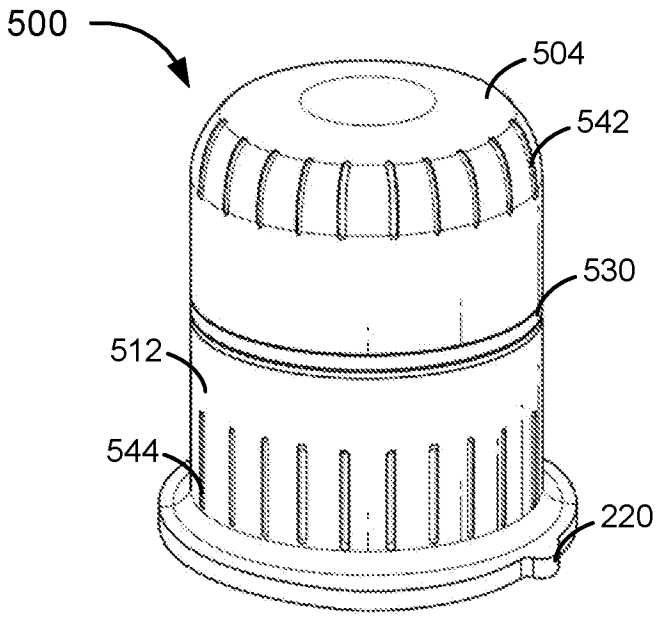

500
504
542
530
512
544
220

FIG. 5A

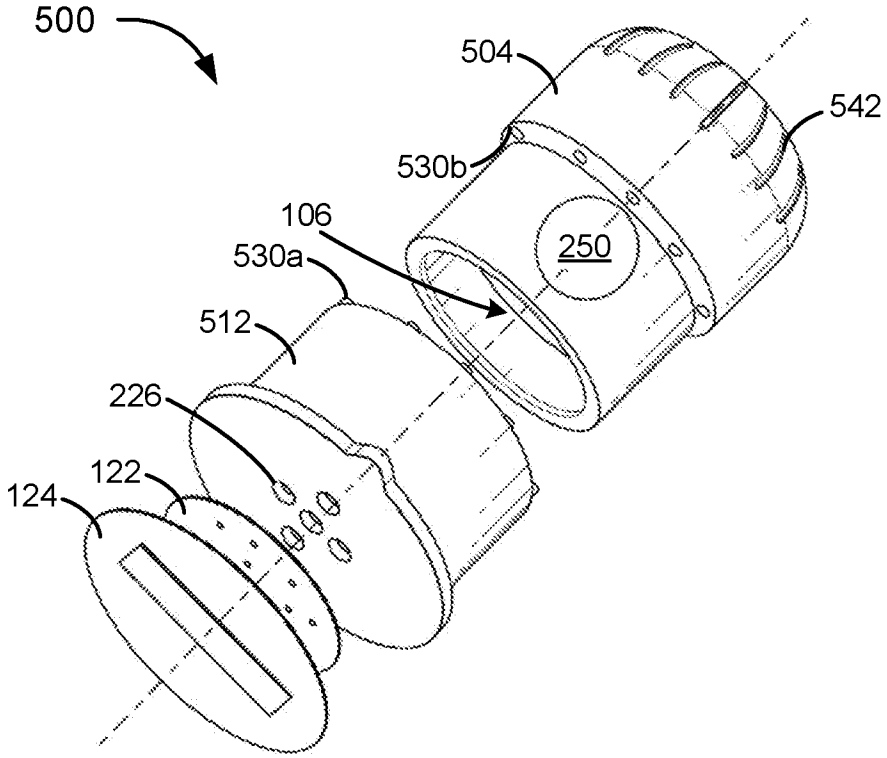

500
504
542
530b
106
250
530a
512
226
122
124

FIG. 5B

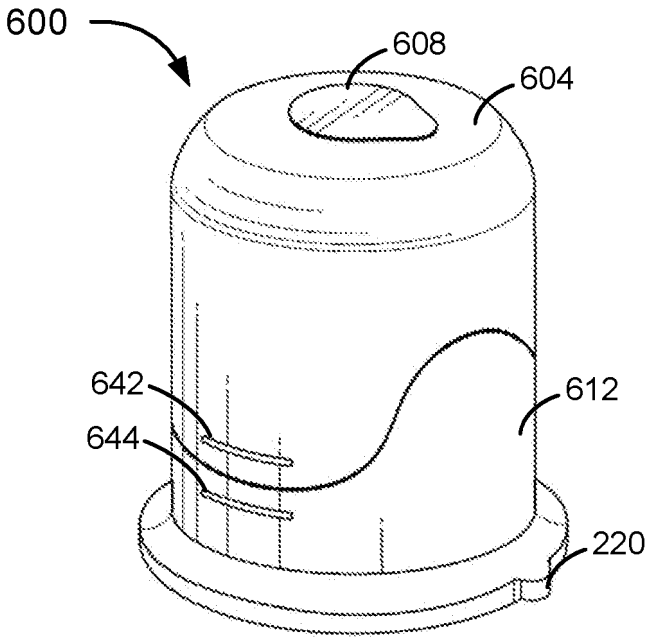


FIG. 6A

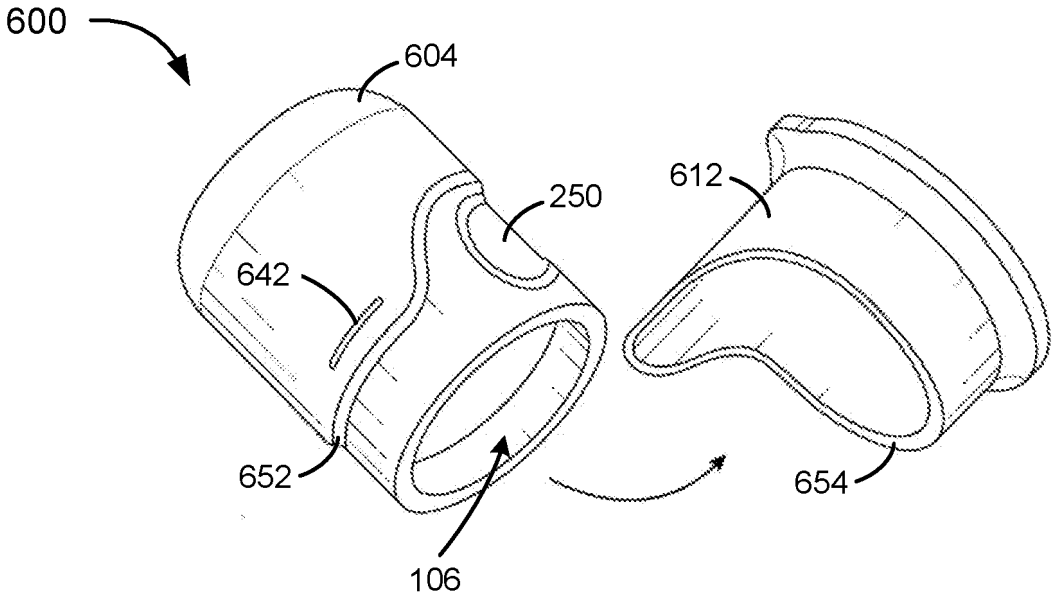


FIG. 6B

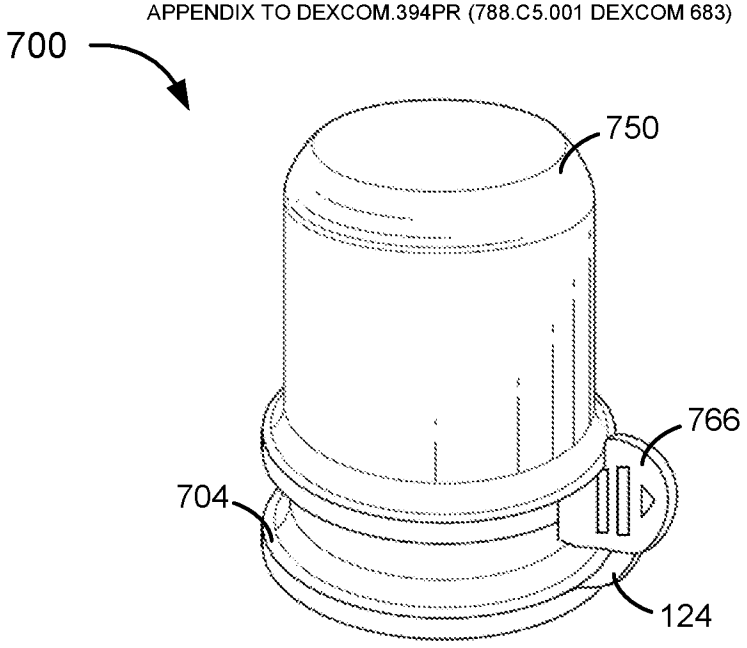


FIG. 7A

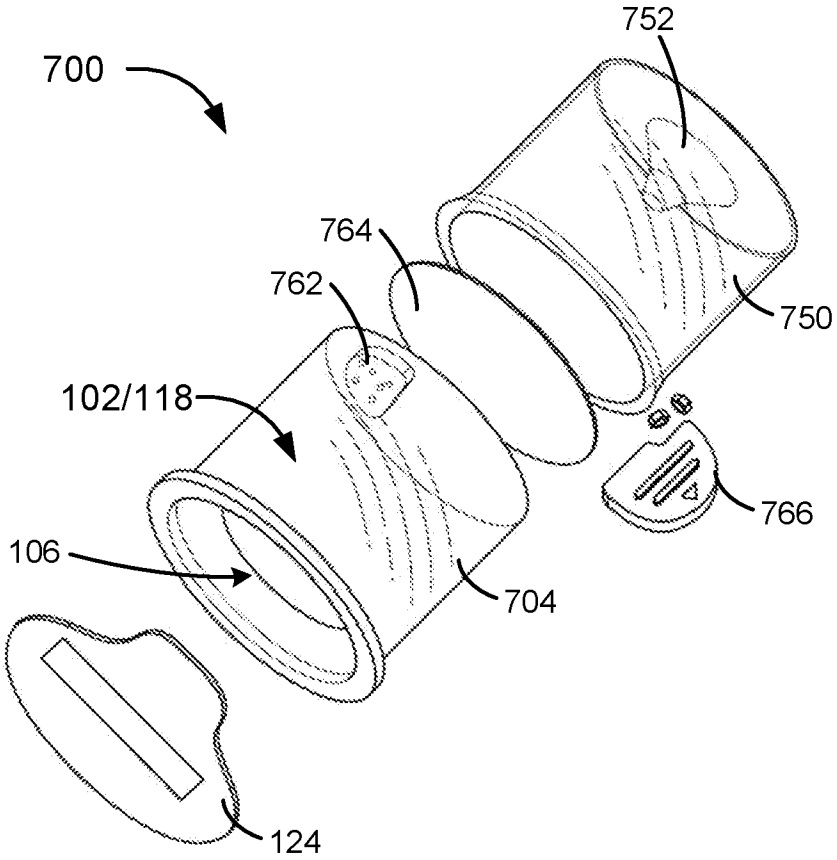


FIG. 7B

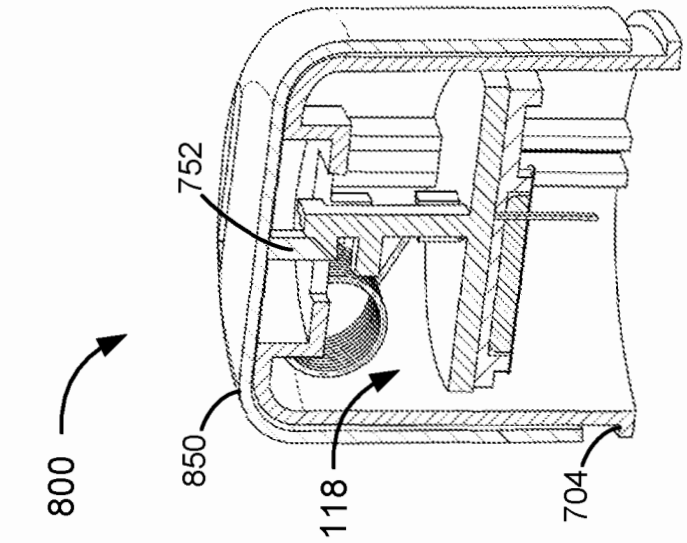


FIG. 8C

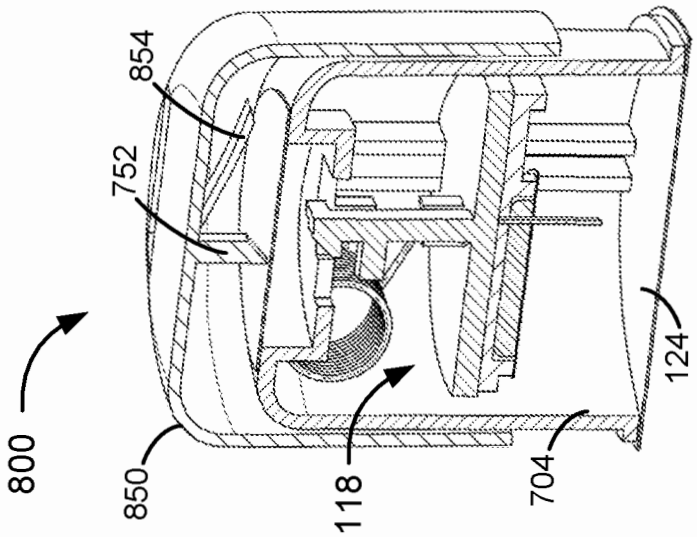


FIG. 8B

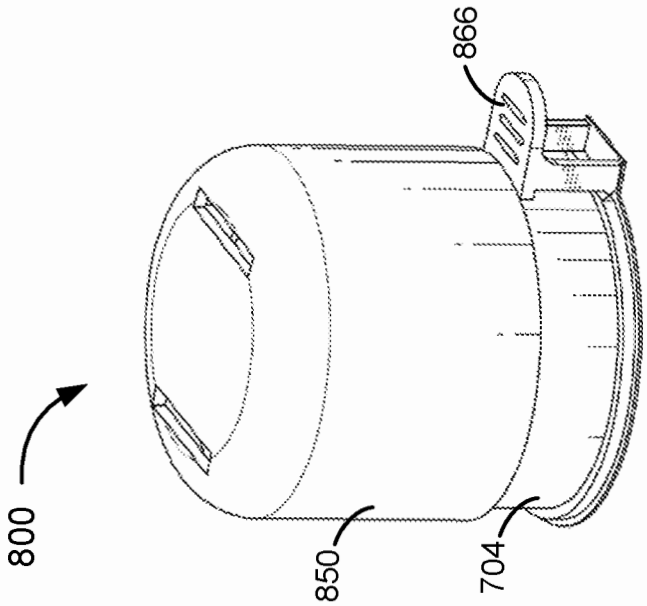


FIG. 8A

788.C3.001

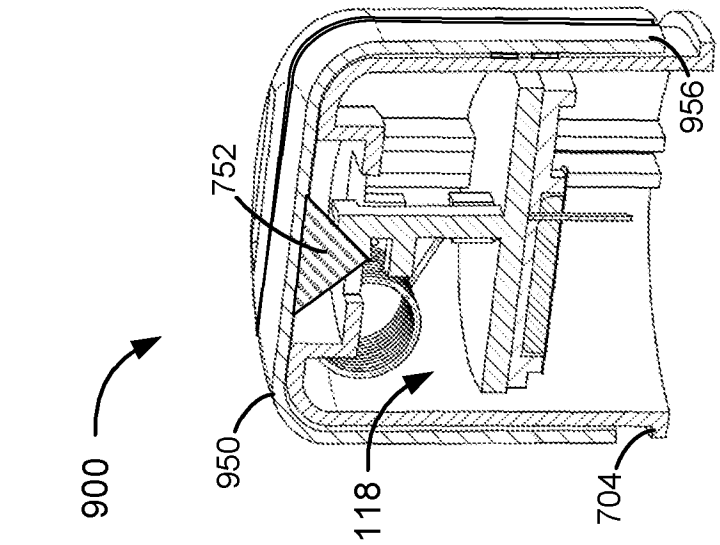


FIG. 9C

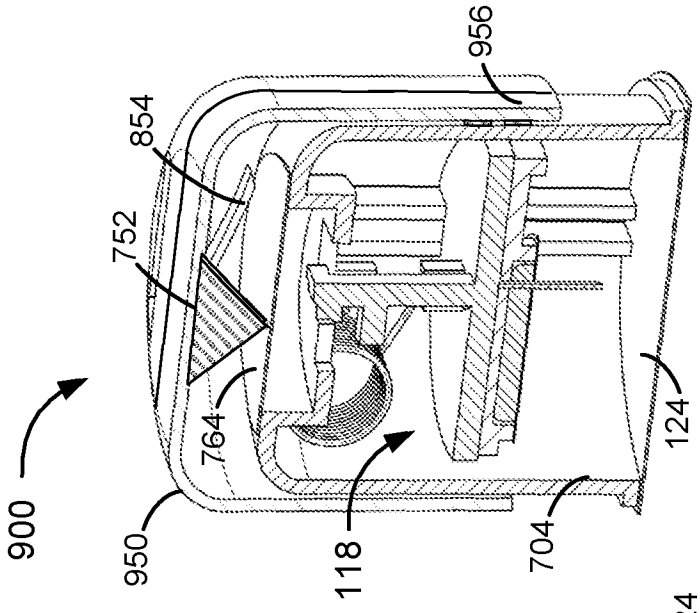


FIG. 9B

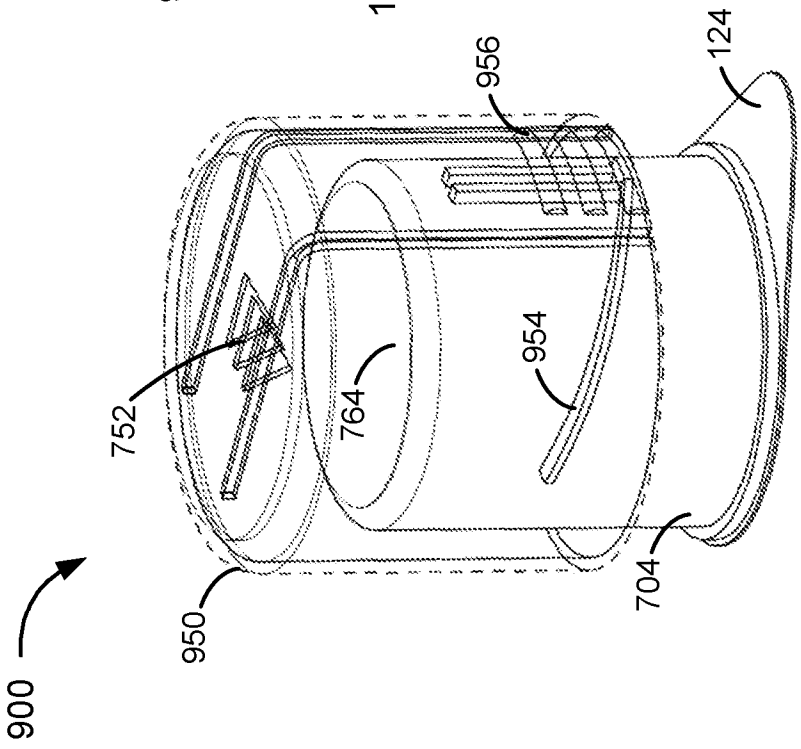


FIG. 9A

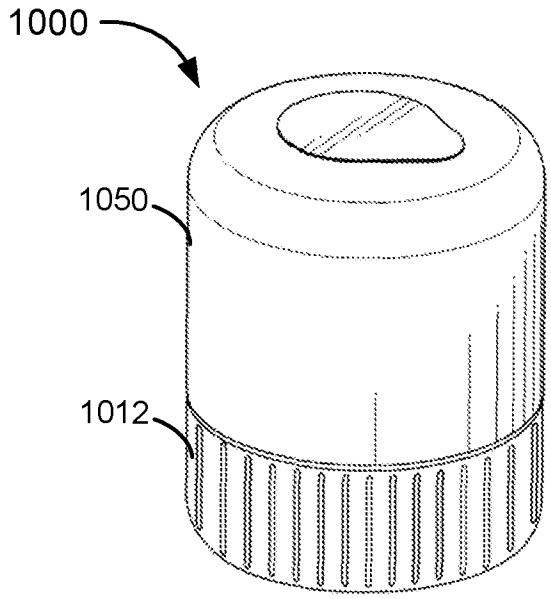


FIG. 10A

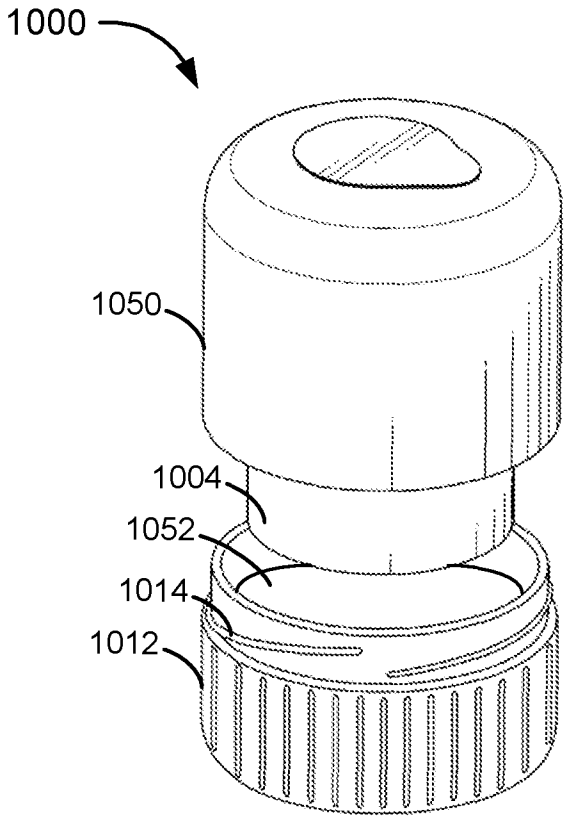


FIG. 10B

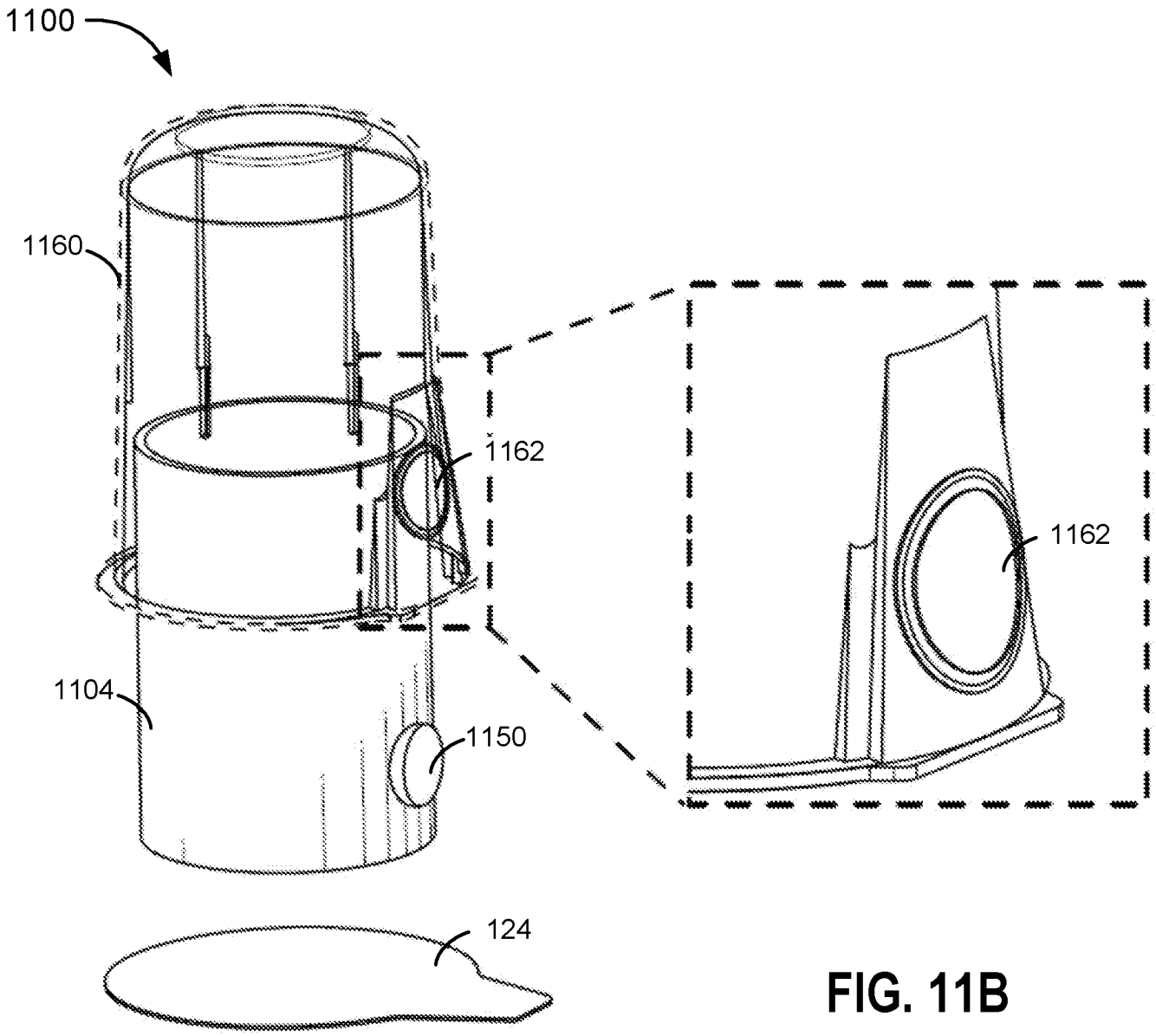


FIG. 11B

FIG. 11A

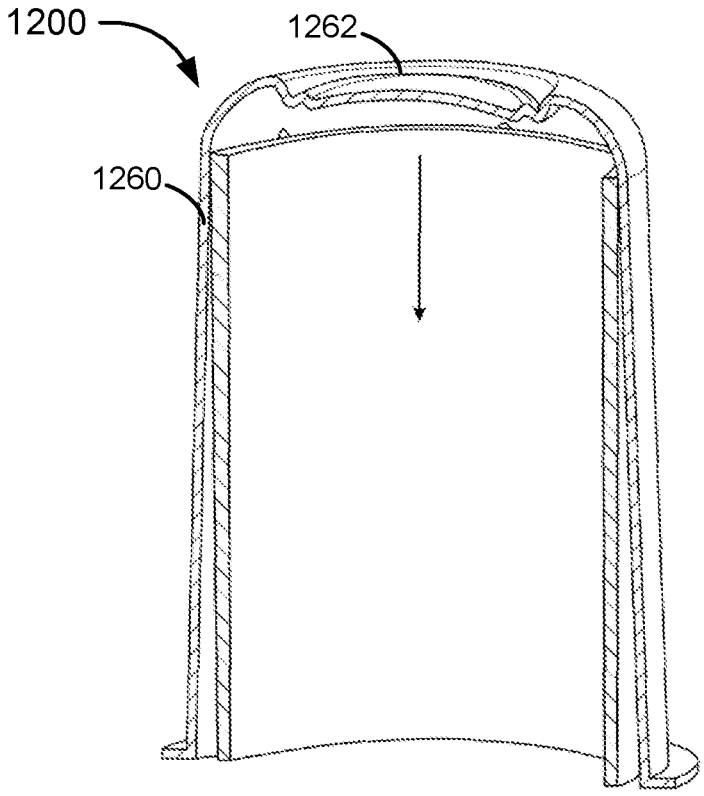


FIG. 12A

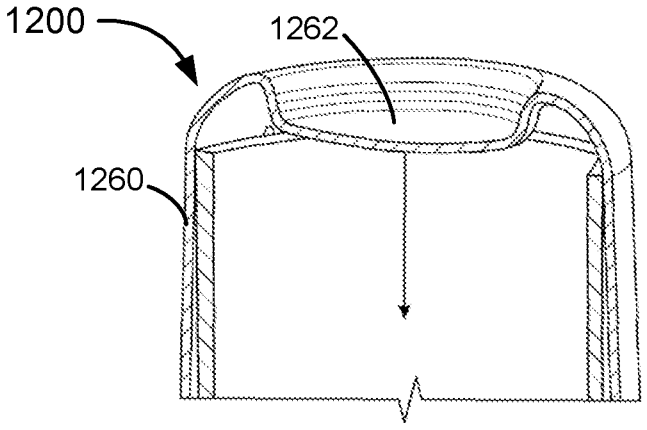


FIG. 12B

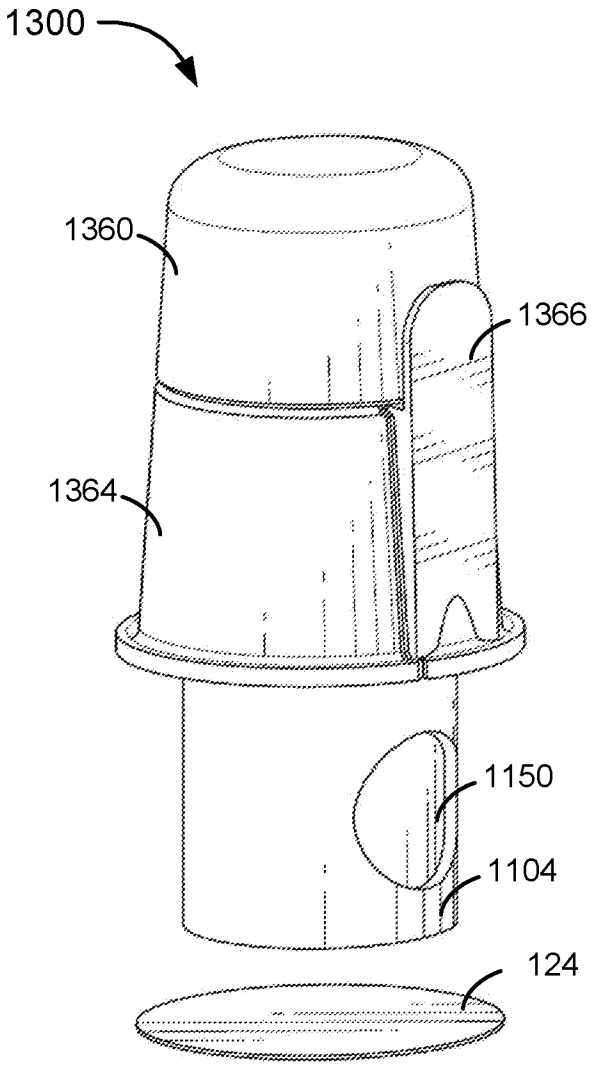


FIG. 13A

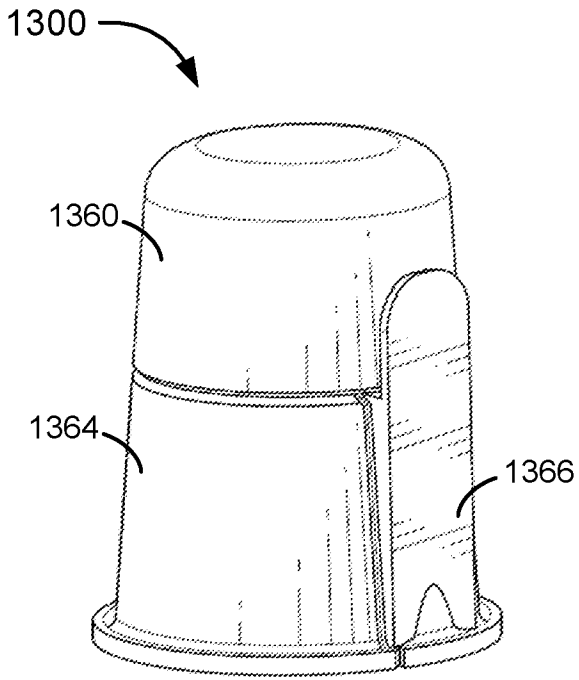


FIG. 13B

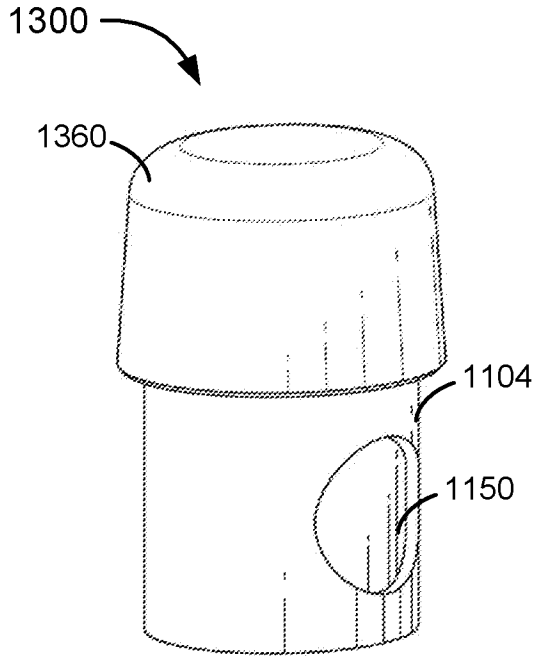


FIG. 13C

APPENDIX TO DEXCOM.394PR (788.C5.001 DEXCOM 683)

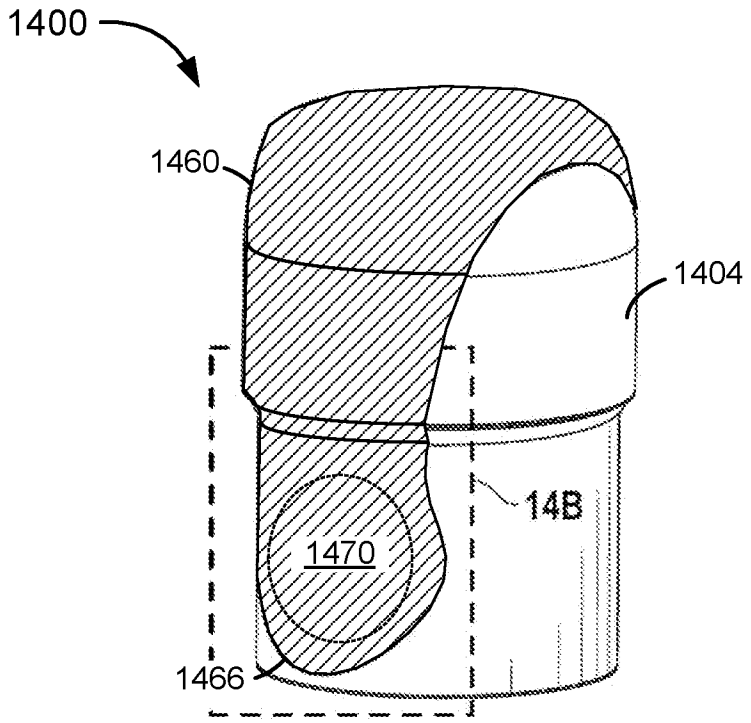


FIG. 14

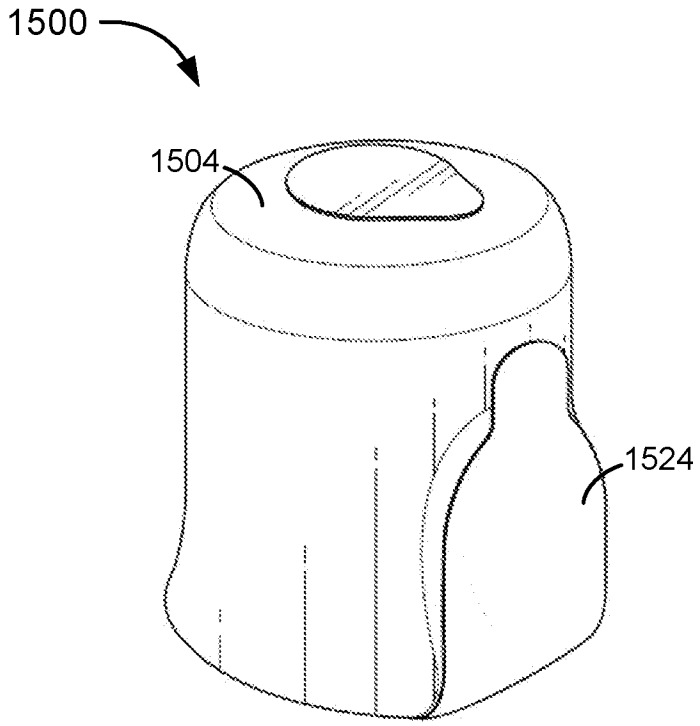


FIG. 15A

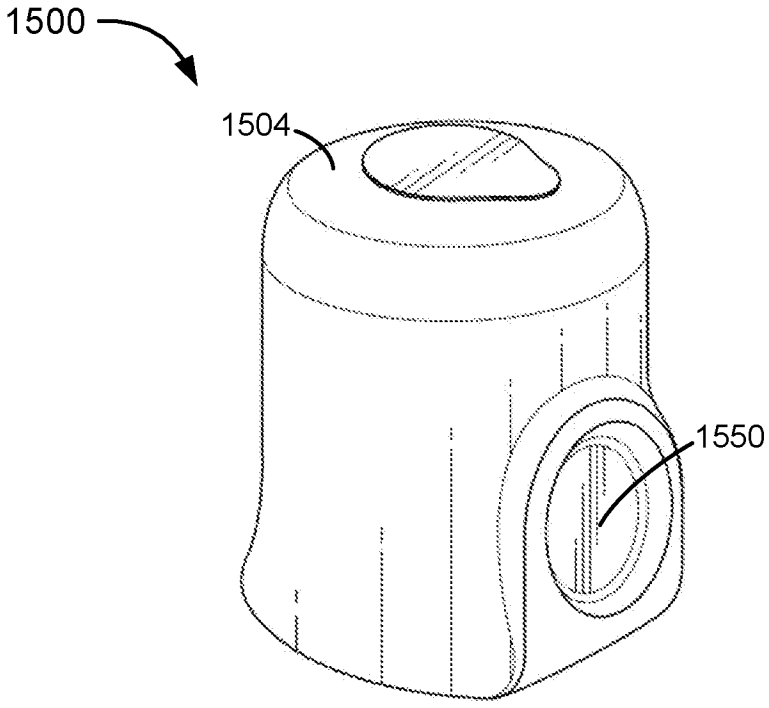


FIG. 15B

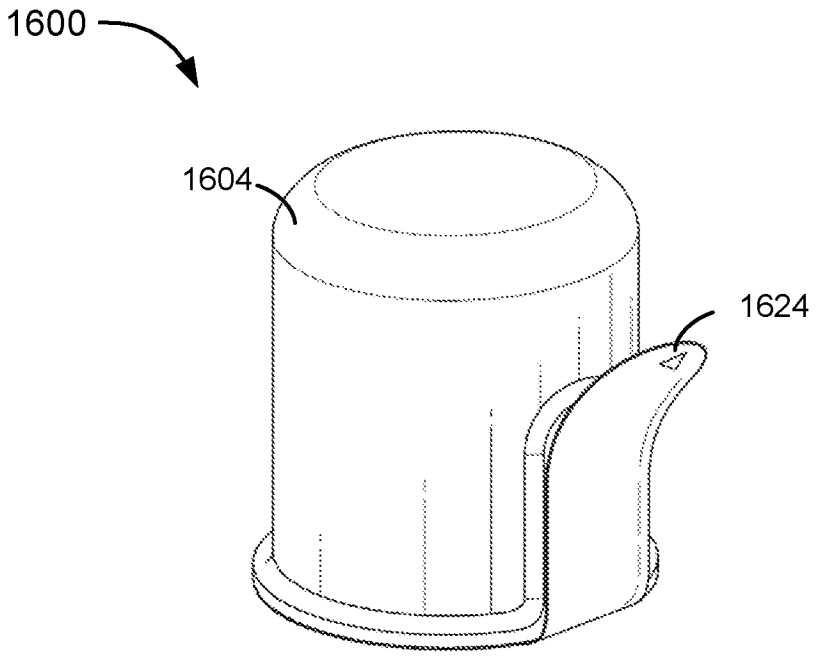


FIG. 16A

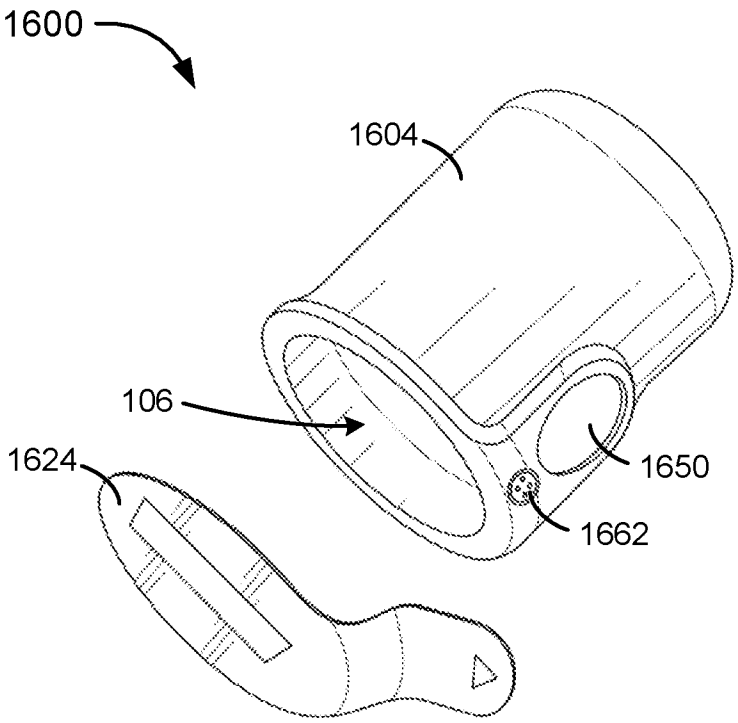


FIG. 16B

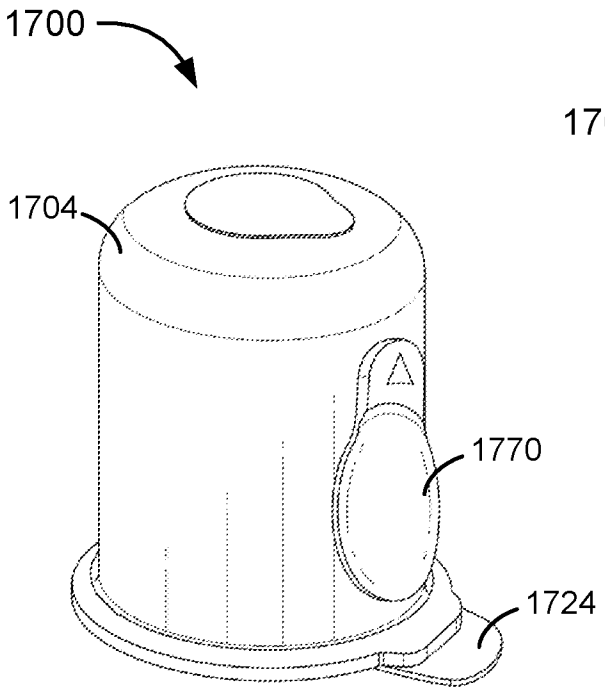


FIG. 17A

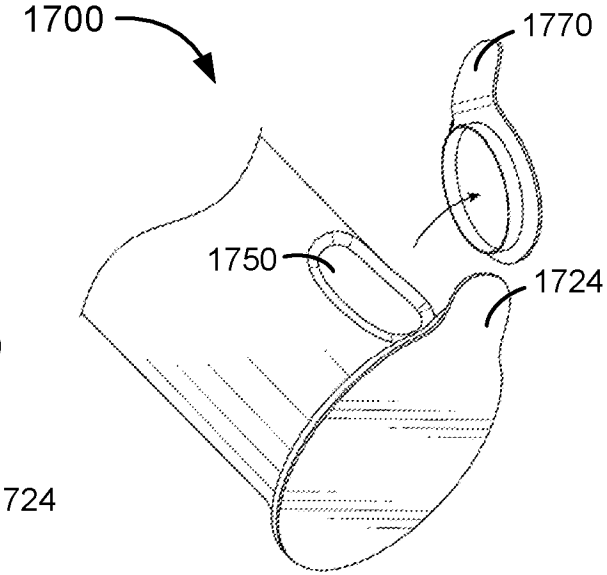


FIG. 17B

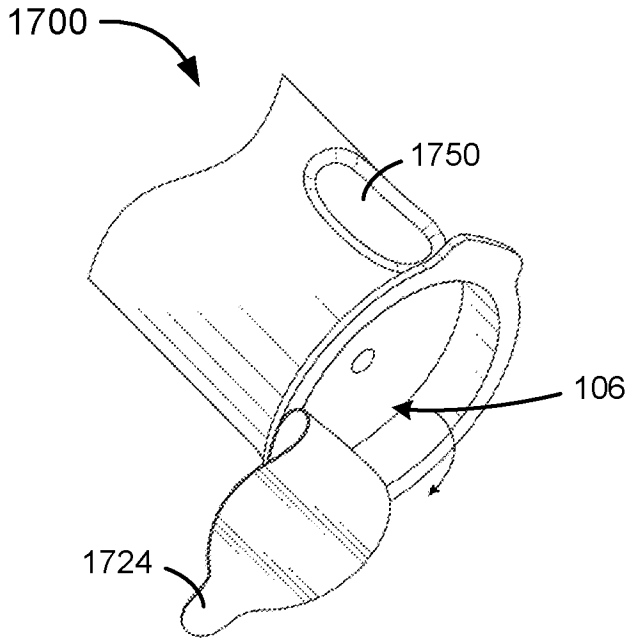


FIG. 17C

APPENDIX TO DEXCOM.394PR (788.C5.001 DEXCOM 683)

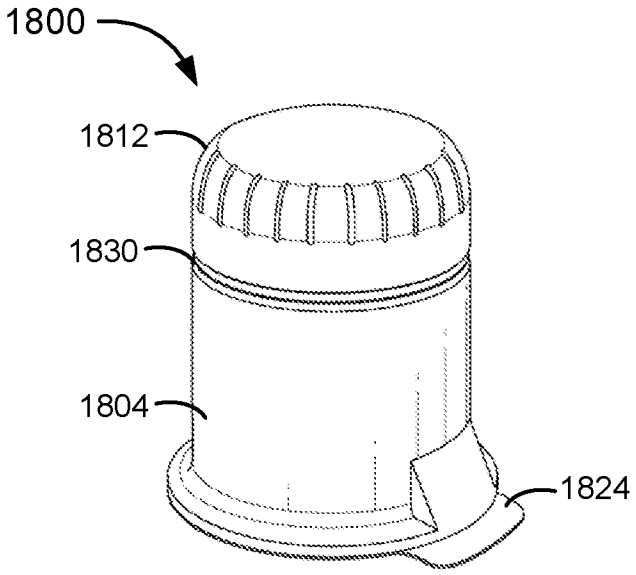


FIG. 18A

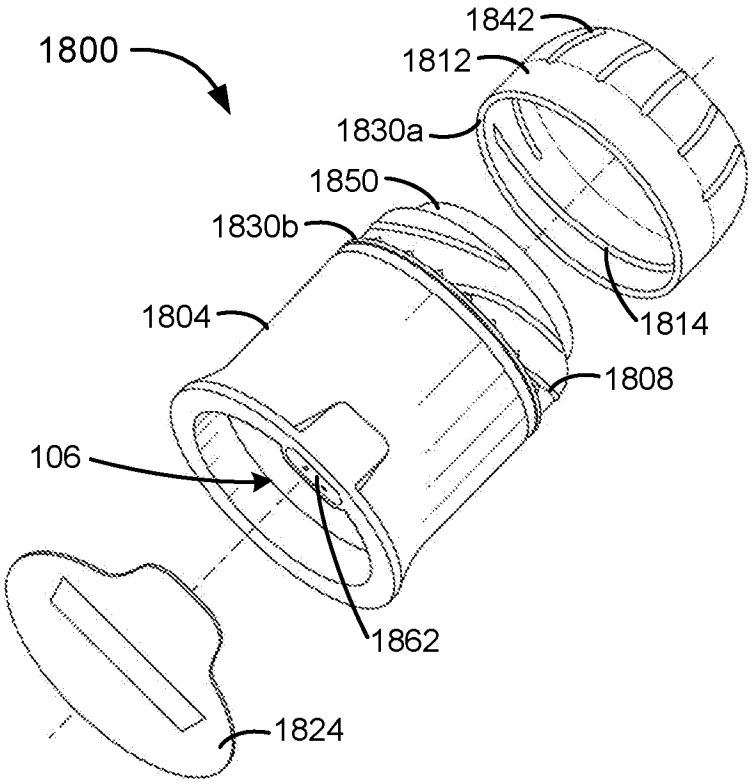


FIG. 18B

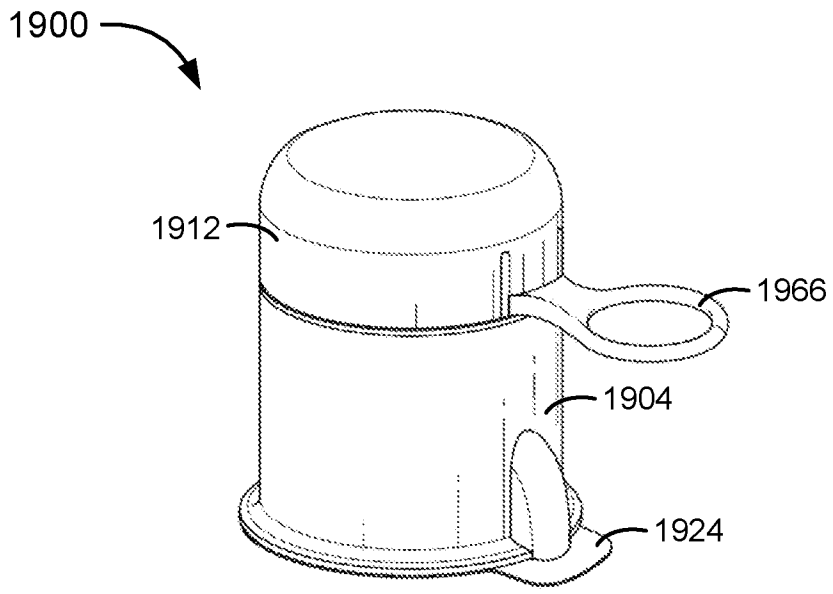


FIG. 19A

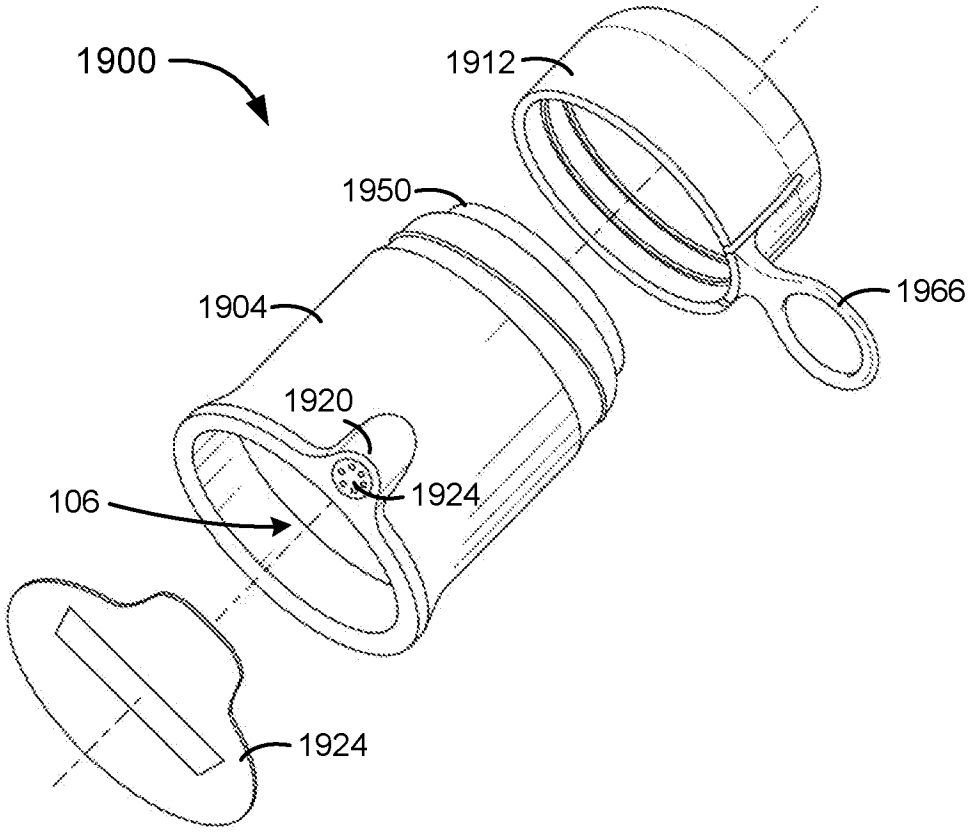


FIG. 19B

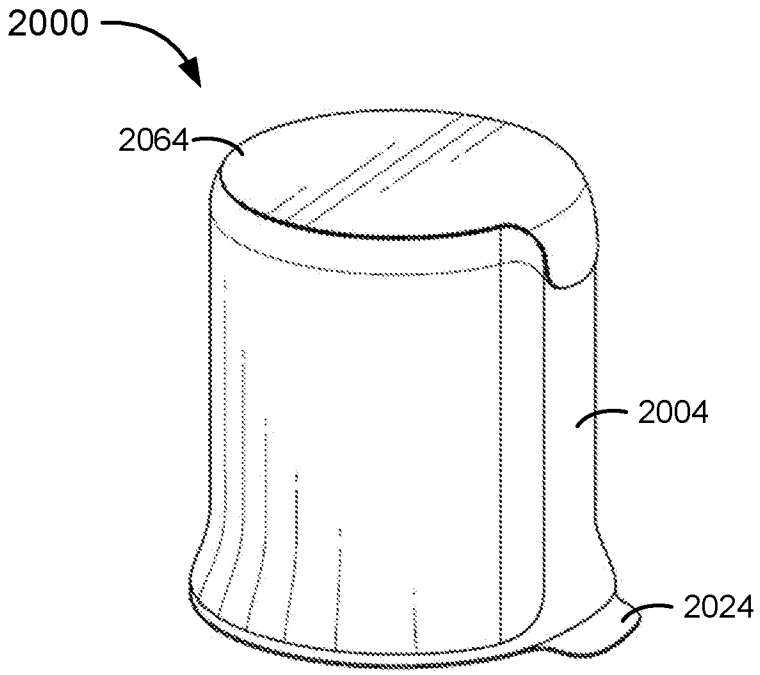


FIG. 20A

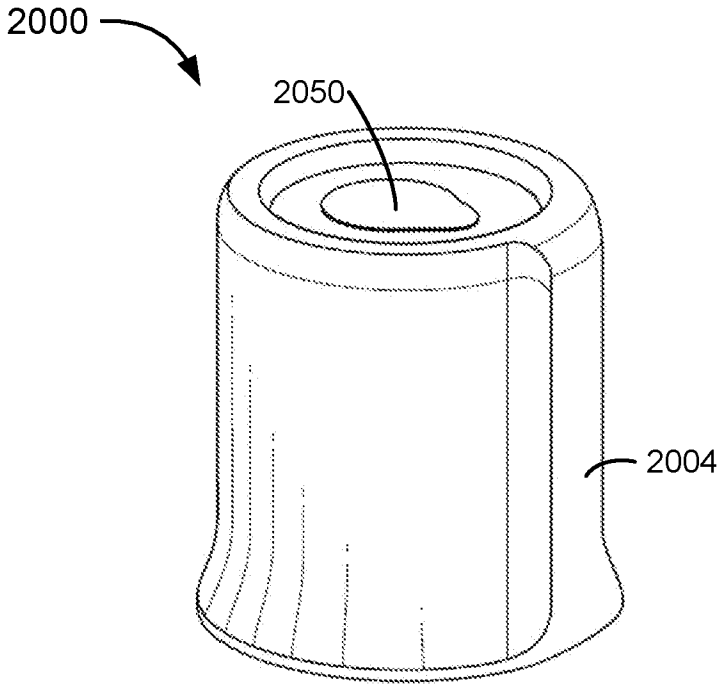


FIG. 20B

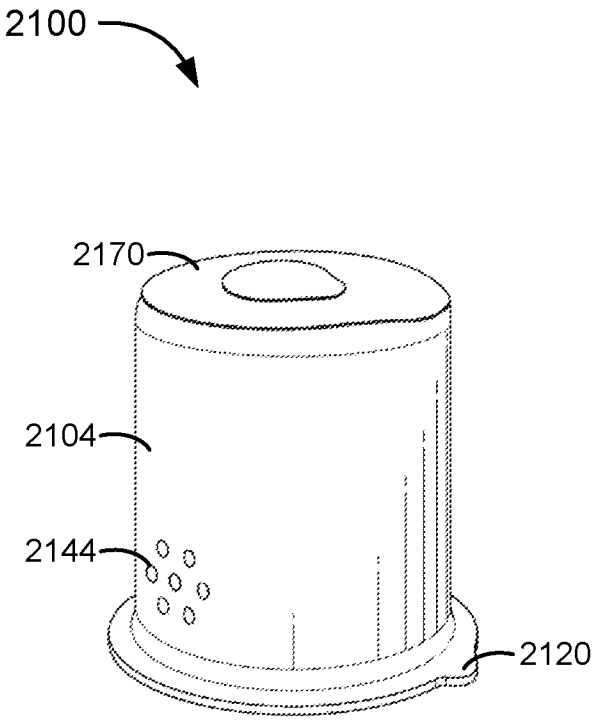


FIG. 21A

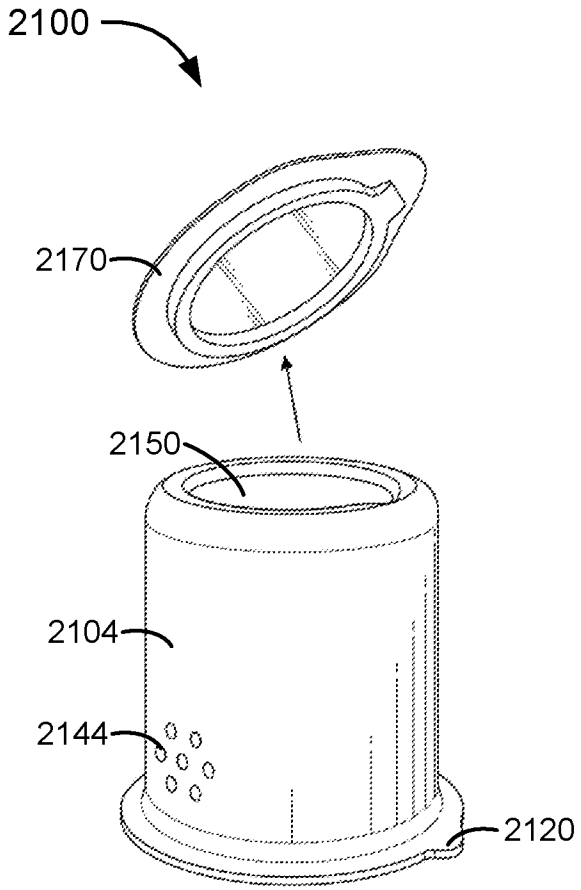


FIG. 21B

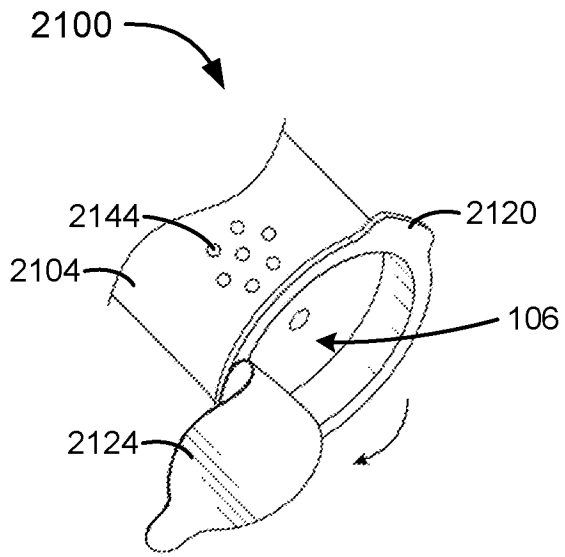


FIG. 21C

APPENDIX TO DEXCOM.394PR (788.C5.001 DEXCOM 683)

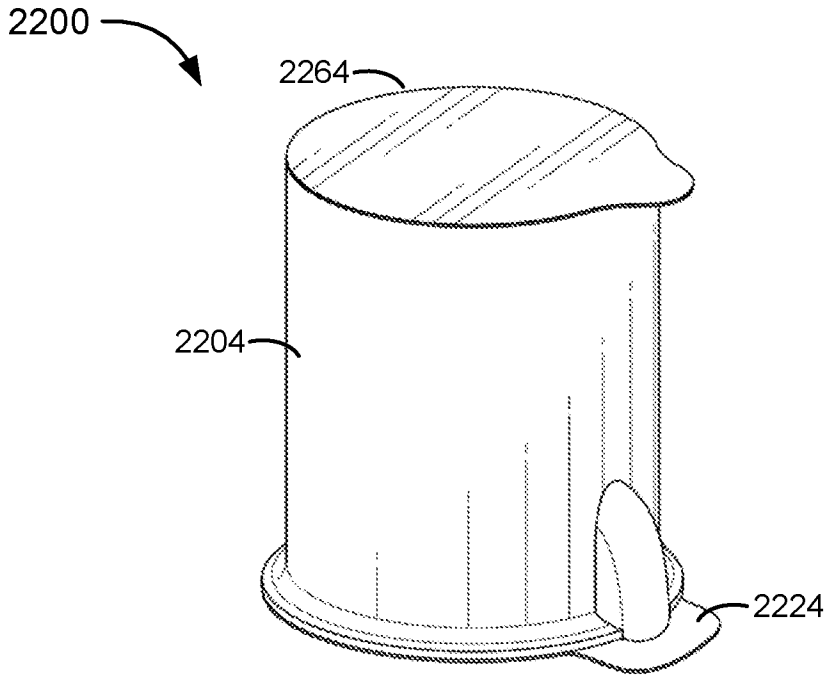


FIG. 22A

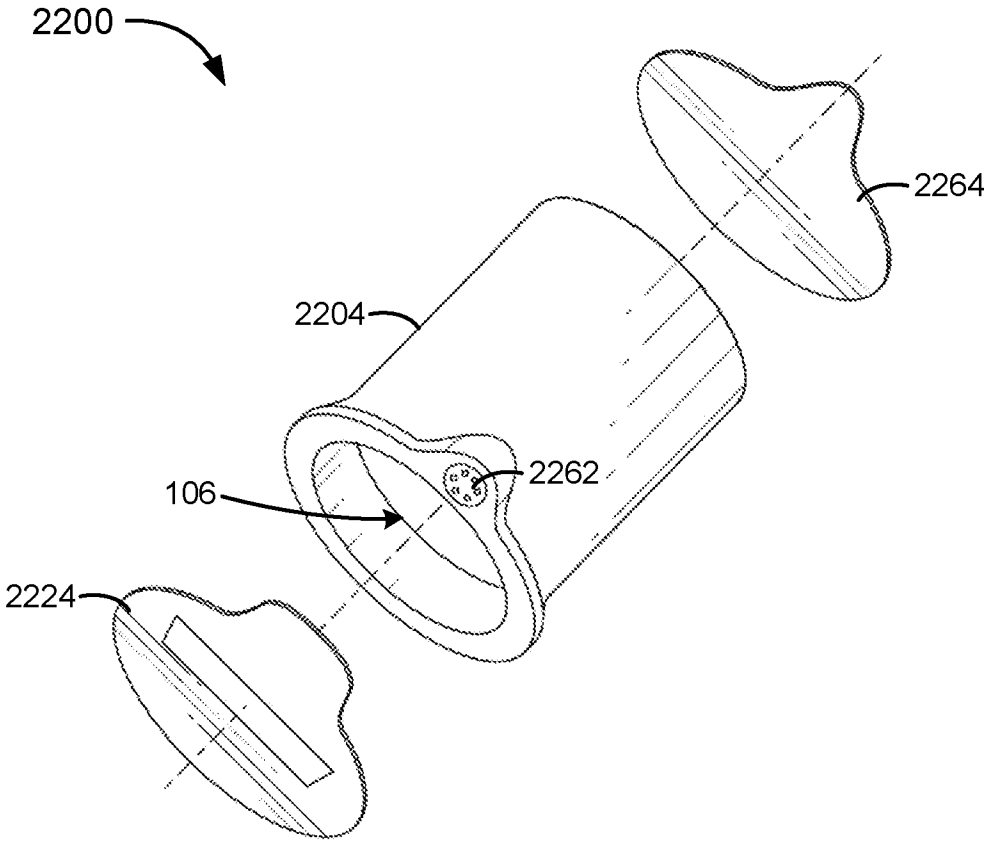


FIG. 22B

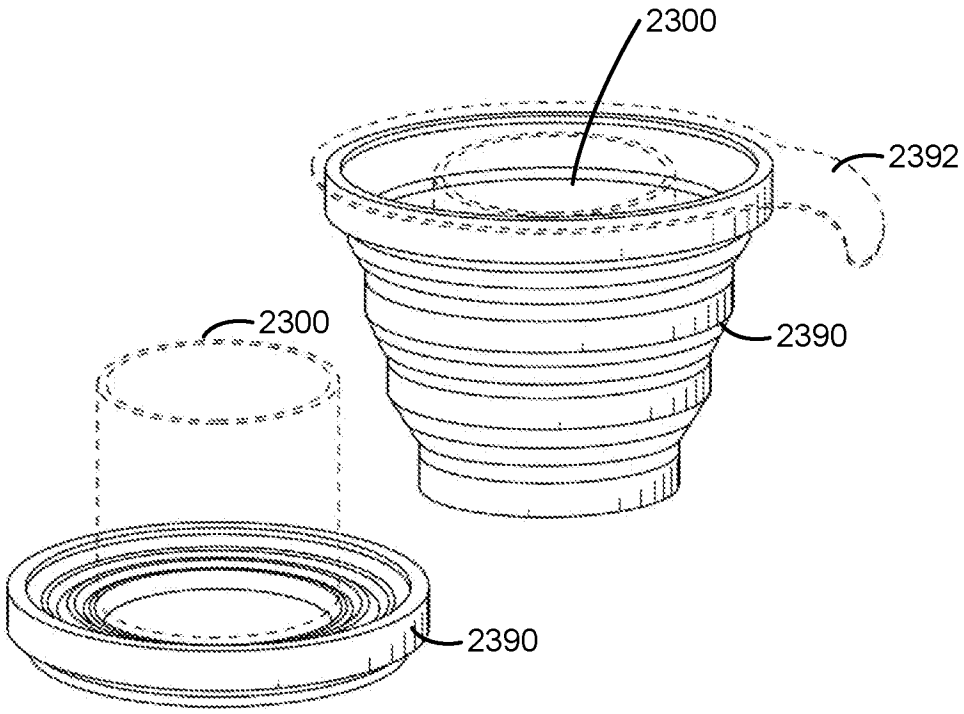


FIG. 23

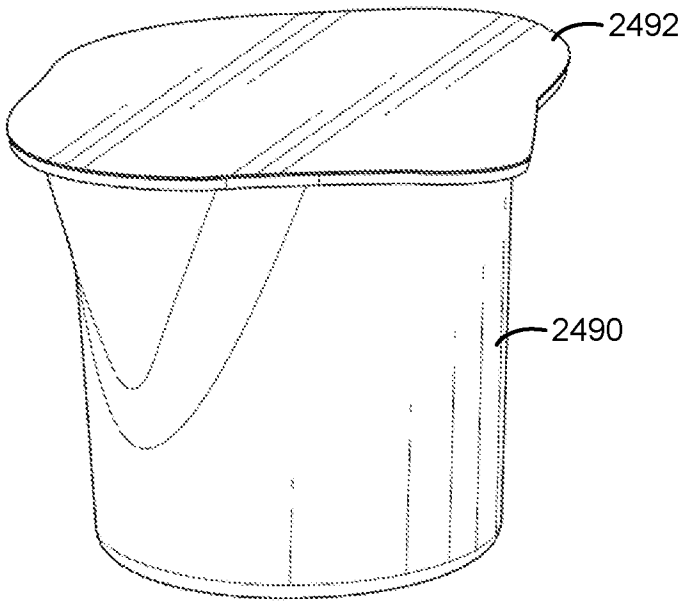


FIG. 24A

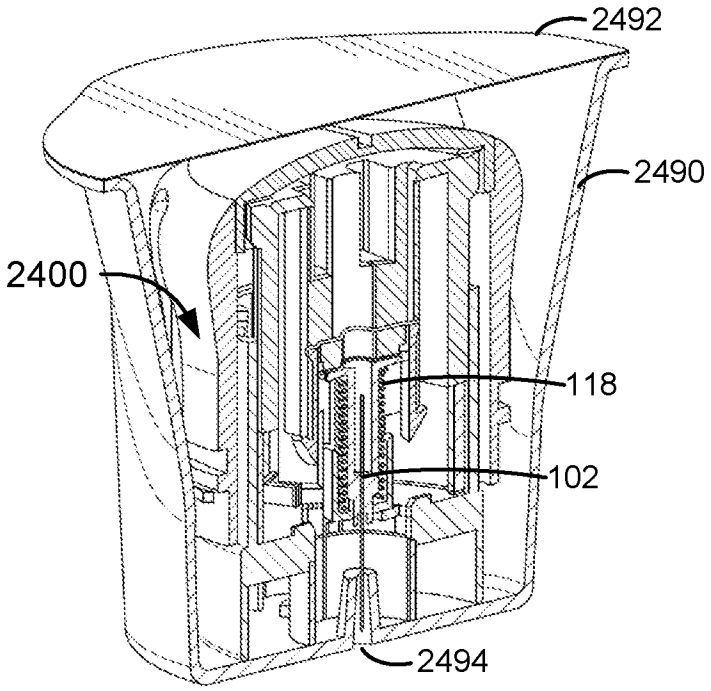


FIG. 24B

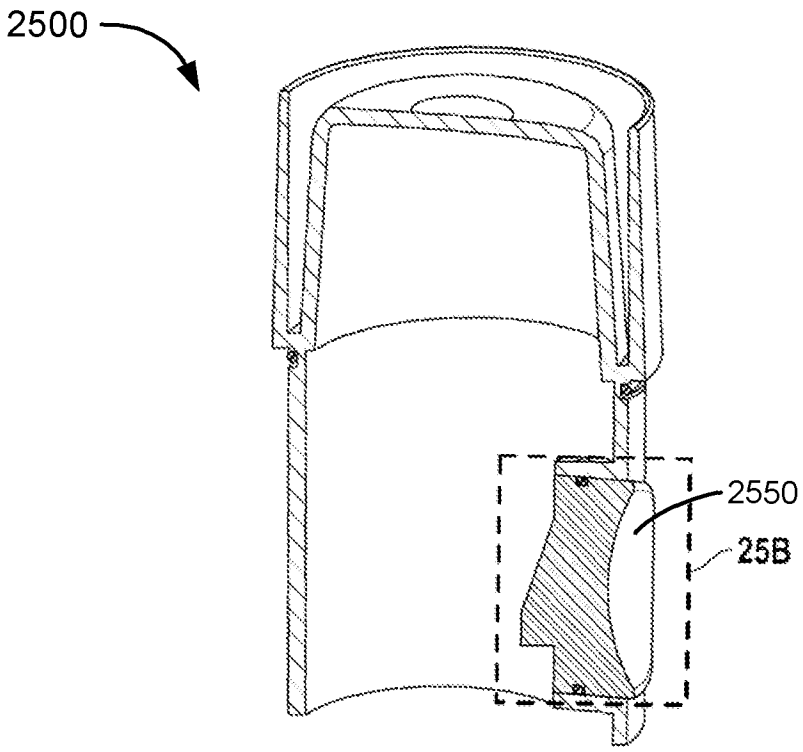


FIG. 25A

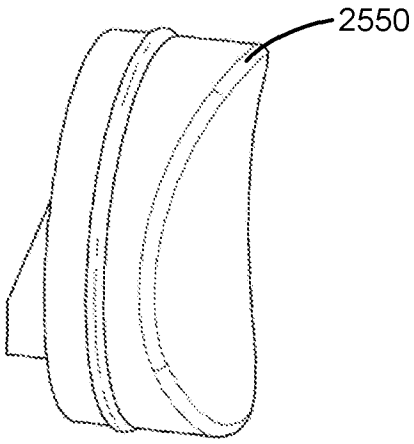


FIG. 25B

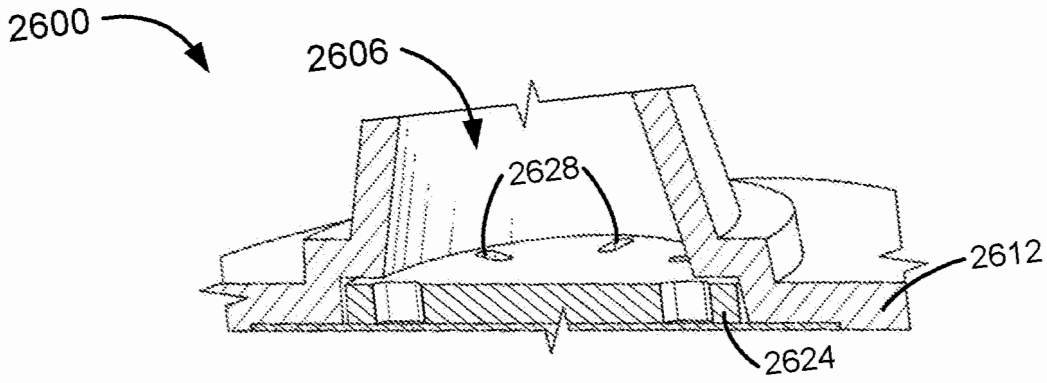


FIG. 26A

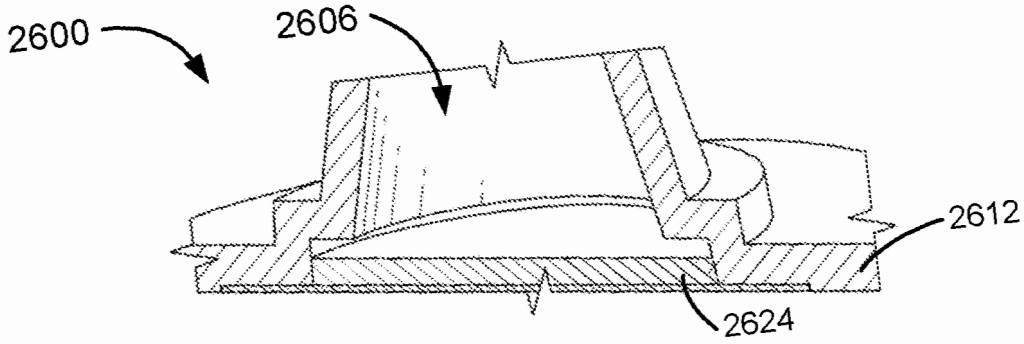


FIG. 26B

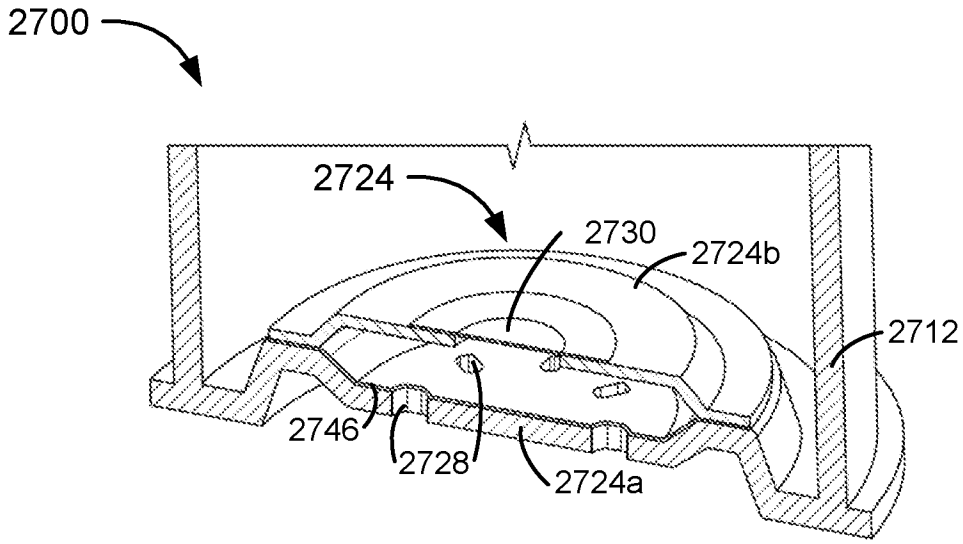


FIG. 27A

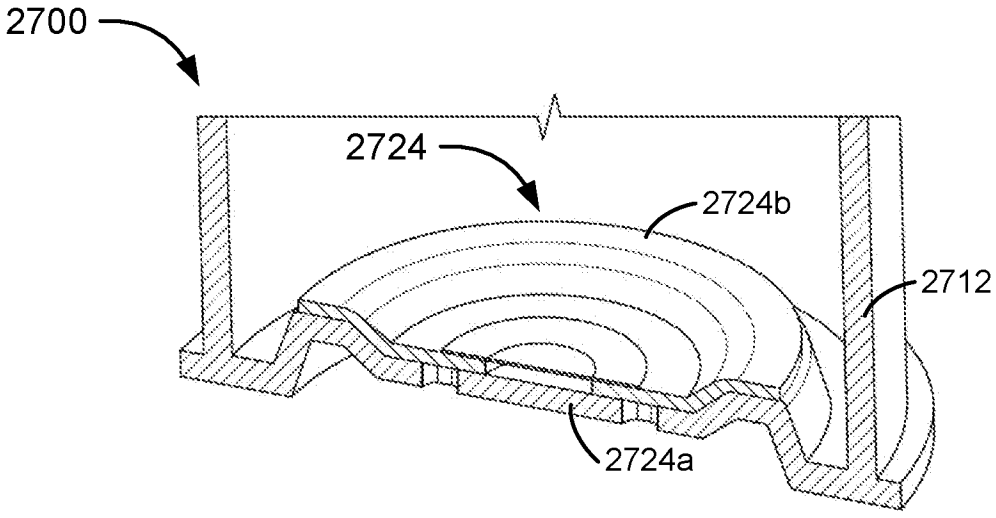


FIG. 27B

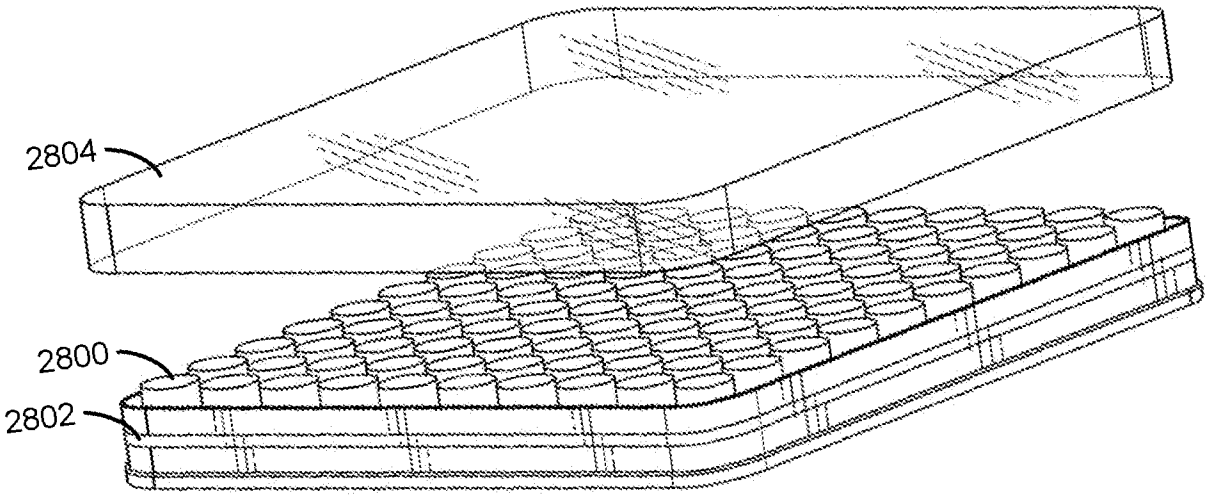


FIG. 28A

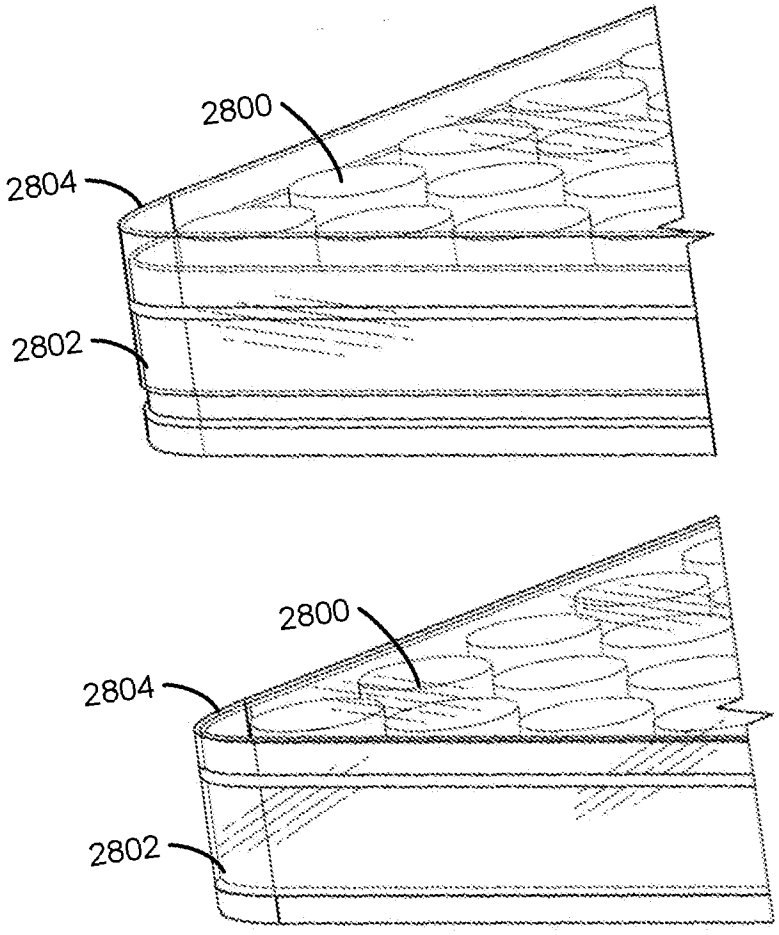


FIG. 28B

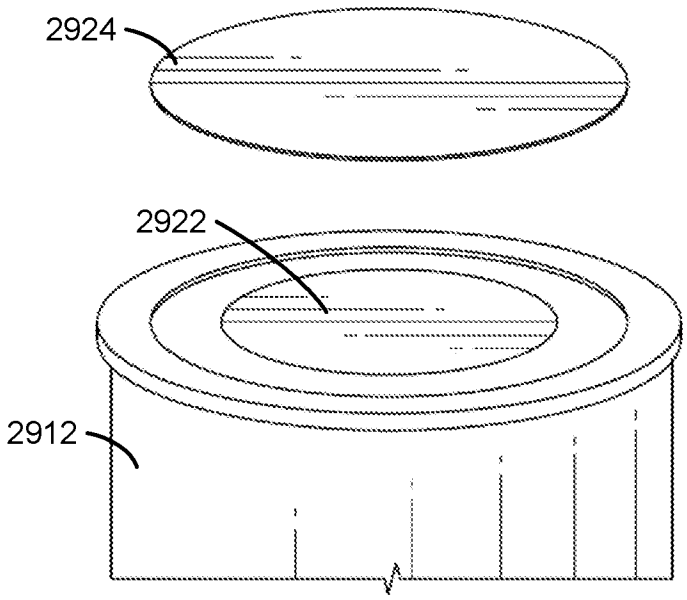


FIG. 29

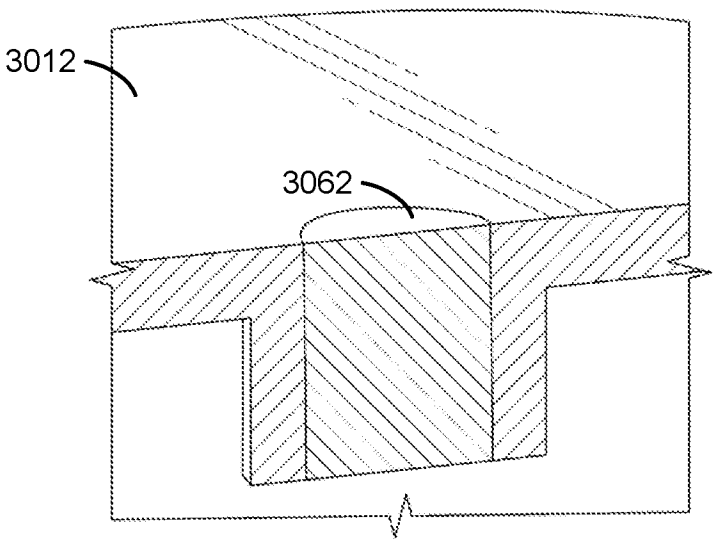


FIG. 30A

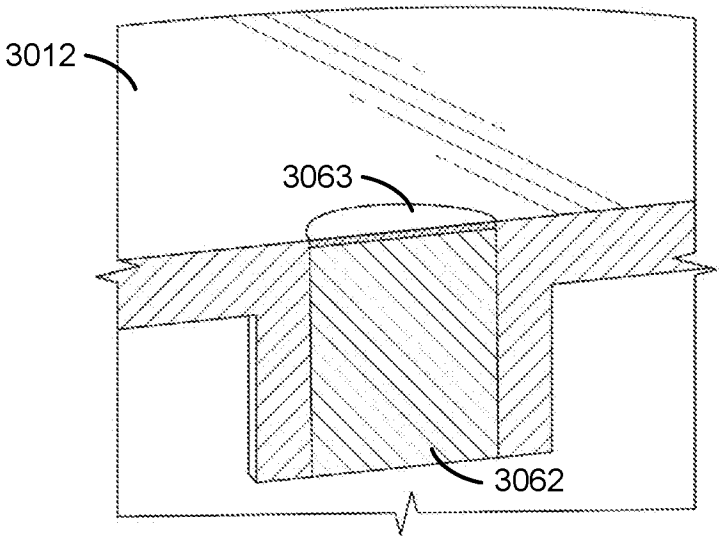


FIG. 30B

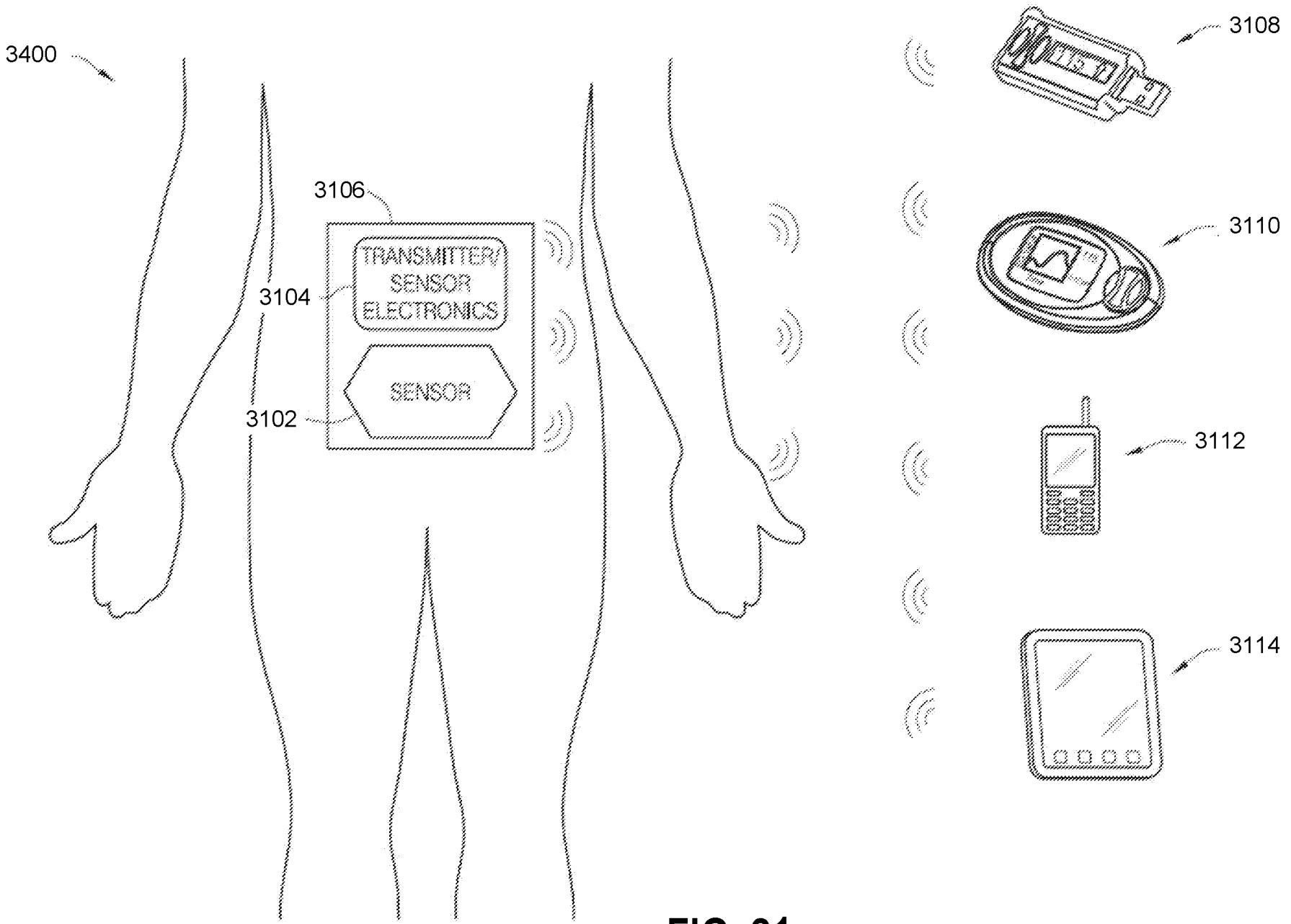


FIG. 31

APPENDIX TO DEXCOM.394PR (788.C5.001 DEXCOM 683)

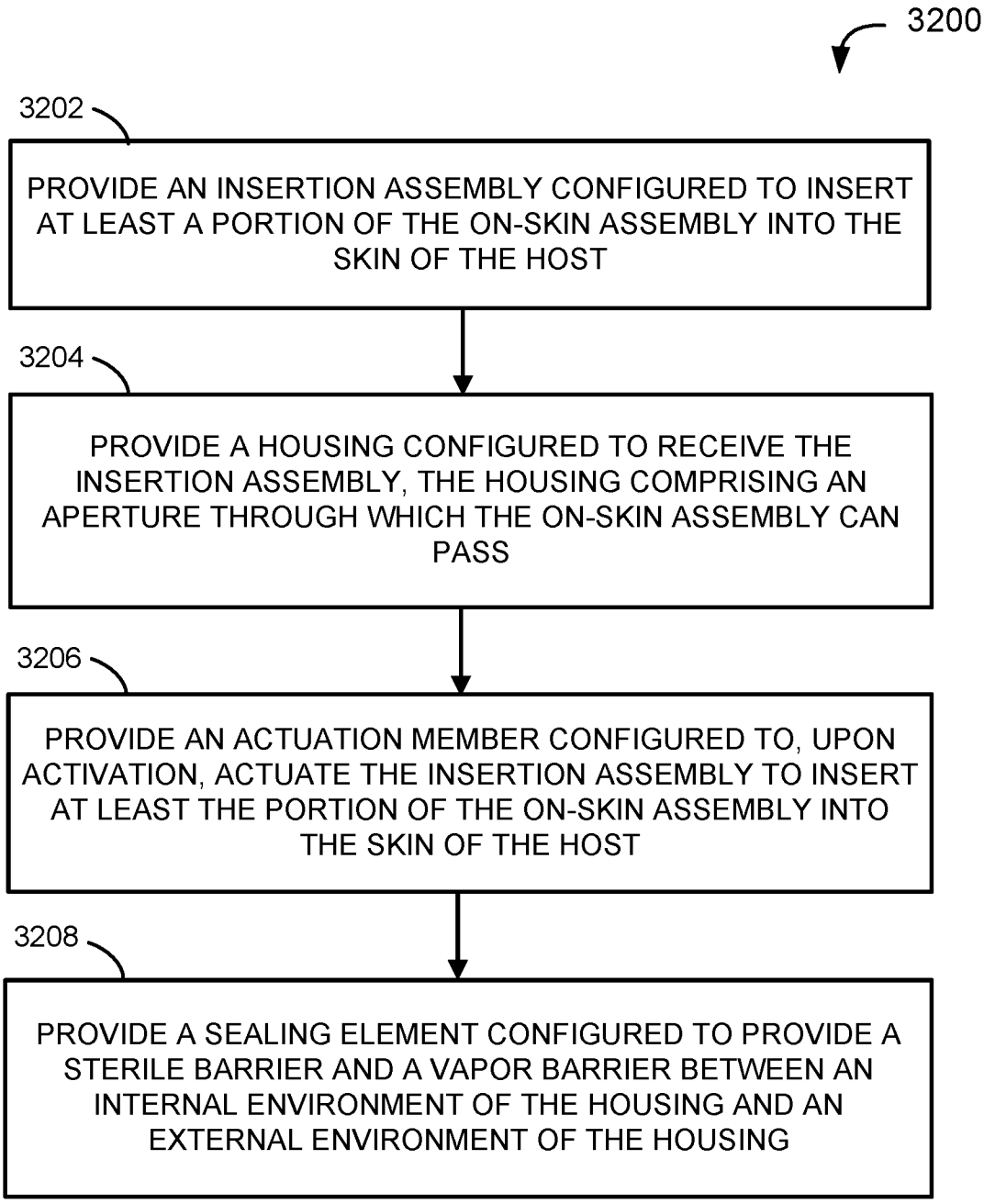

3200
3202
PROVIDE AN INSERTION ASSEMBLY CONFIGURED TO INSERT AT LEAST A PORTION OF THE ON-SKIN ASSEMBLY INTO THE SKIN OF THE HOST
3204
PROVIDE A HOUSING CONFIGURED TO RECEIVE THE INSERTION ASSEMBLY, THE HOUSING COMPRISING AN APERTURE THROUGH WHICH THE ON-SKIN ASSEMBLY CAN PASS
3206
PROVIDE AN ACTUATION MEMBER CONFIGURED TO, UPON ACTIVATION, ACTUATE THE INSERTION ASSEMBLY TO INSERT AT LEAST THE PORTION OF THE ON-SKIN ASSEMBLY INTO THE SKIN OF THE HOST
3208
PROVIDE A SEALING ELEMENT CONFIGURED TO PROVIDE A STERILE BARRIER AND A VAPOR BARRIER BETWEEN AN INTERNAL ENVIRONMENT OF THE HOUSING AND AN EXTERNAL ENVIRONMENT OF THE HOUSING

FIG. 32

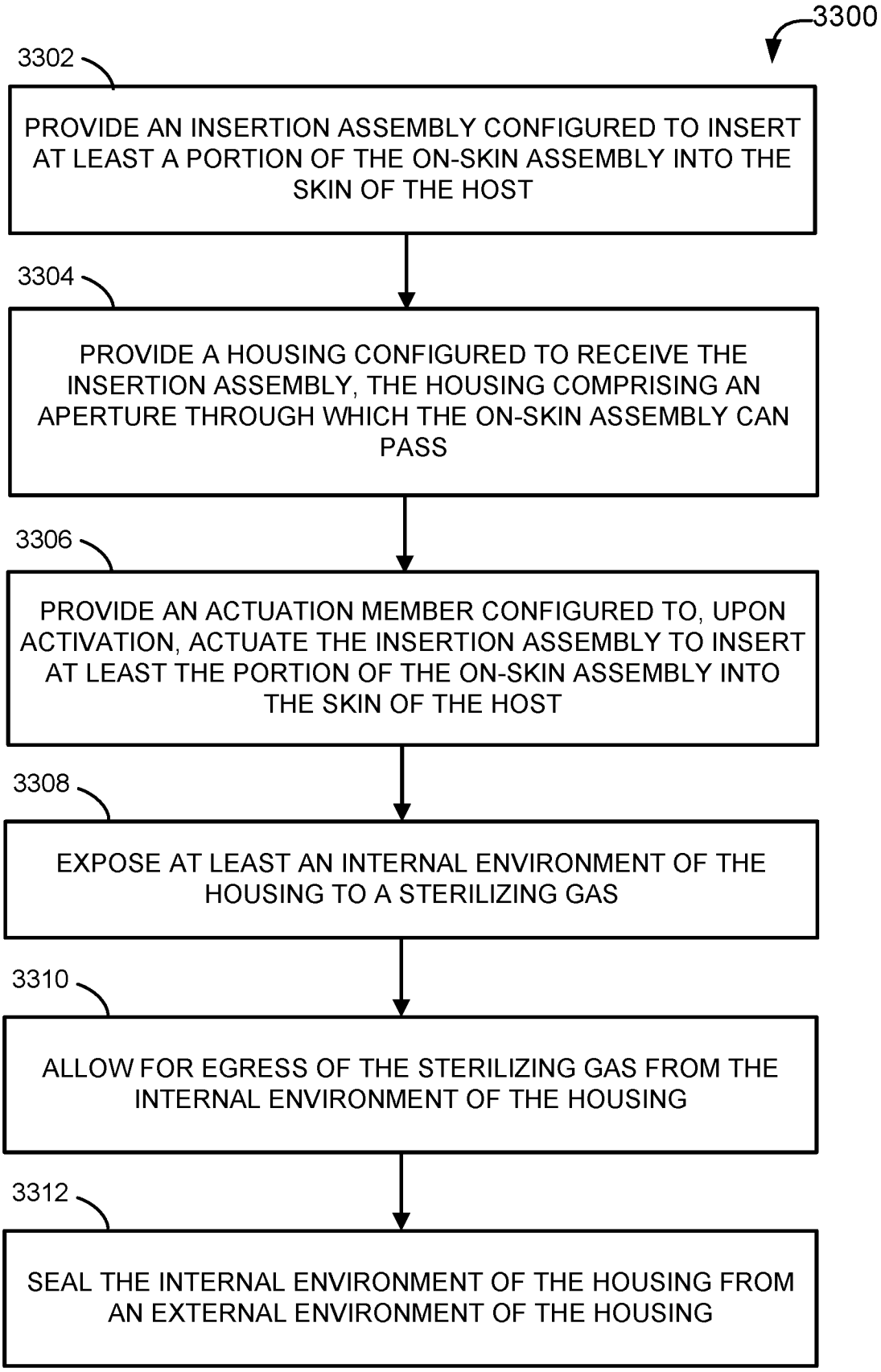

3300
3302
PROVIDE AN INSERTION ASSEMBLY CONFIGURED TO INSERT AT LEAST A PORTION OF THE ON-SKIN ASSEMBLY INTO THE SKIN OF THE HOST
3304
PROVIDE A HOUSING CONFIGURED TO RECEIVE THE INSERTION ASSEMBLY, THE HOUSING COMPRISING AN APERTURE THROUGH WHICH THE ON-SKIN ASSEMBLY CAN PASS
3306
PROVIDE AN ACTUATION MEMBER CONFIGURED TO, UPON ACTIVATION, ACTUATE THE INSERTION ASSEMBLY TO INSERT AT LEAST THE PORTION OF THE ON-SKIN ASSEMBLY INTO THE SKIN OF THE HOST
3308
EXPOSE AT LEAST AN INTERNAL ENVIRONMENT OF THE HOUSING TO A STERILIZING GAS
3310
ALLOW FOR EGRESS OF THE STERILIZING GAS FROM THE INTERNAL ENVIRONMENT OF THE HOUSING
3312
SEAL THE INTERNAL ENVIRONMENT OF THE HOUSING FROM AN EXTERNAL ENVIRONMENT OF THE HOUSING

FIG. 33

TRANSCUTANEOUS ANALYTE SENSOR SYSTEMS AND METHODS

INCORPORATION BY REFERENCE TO RELATED APPLICATIONS

[0001] Any and all priority claims identified in the Application Data Sheet, or any correction thereto, are hereby incorporated by reference under 37 CFR 1.57. This application claims the benefit of U.S. Provisional Application No. 62/272,983, filed December 30, 2015 and U.S. Provisional Application No. 62/412,100, filed October 24, 2016. Each of the aforementioned applications is incorporated by reference herein in its entirety, and each is hereby expressly made a part of this specification.

FIELD

[0002] Various embodiments disclosed herein relate to measuring an analyte in a person. Certain embodiments relate to systems and methods for applying a transcutaneous analyte measurement system to a person.

BACKGROUND

[0003] Diabetes mellitus is a disorder in which the pancreas cannot create sufficient insulin (Type I or insulin dependent) and/or in which insulin is not effective (Type 2 or non-insulin dependent). In the diabetic state, the victim suffers from high blood sugar, which can cause an array of physiological derangements associated with the deterioration of small blood vessels, for example, kidney failure, skin ulcers, or bleeding into the vitreous of the eye. A hypoglycemic reaction (low blood sugar) can be induced by an inadvertent overdose of insulin, or after a normal dose of insulin or glucose-lowering agent accompanied by extraordinary exercise or insufficient food intake.

[0004] Conventionally, a person with diabetes carries a self-monitoring blood glucose monitor, which typically requires uncomfortable finger pricking methods. Due to the lack of comfort and convenience, a person with diabetes normally only measures his or her glucose levels two to four times per day. Unfortunately, such time intervals are so far spread apart that the person with diabetes likely finds out too late of a hyperglycemic or hypoglycemic condition, sometimes incurring dangerous side effects. Glucose levels may be alternatively monitored continuously by a sensor system including an on-skin sensor assembly. The sensor system may have a wireless transmitter which transmits measurement data to a receiver which can process and display information based on the measurements.

[0005] The process of applying the sensor to the person is important for such a system to be effective and user friendly. The application process can result in the sensor assembly being attached to the person in a state where it is capable of sensing glucose level information, communicating the glucose level information to the transmitter, and transmitting the glucose level information to the receiver.

[0006] The analyte sensor can be placed into subcutaneous tissue. A user can actuate an applicator to insert the analyte sensor into its functional location. This transcutaneous insertion can lead to incomplete sensor insertion, improper sensor insertion, exposed needles, or unnecessary pain. Thus, there is a need for a system that more reliably enables transcutaneous sensor insertion while being easy to use and relatively pain-free.

SUMMARY

[0007] Various systems and methods described herein enable reliable, simple, and pain-minimizing transcutaneous insertion of analyte sensors. Some embodiments are a system for applying an on-skin sensor assembly to skin of a host. Systems can comprise a telescoping assembly having a first portion configured to move distally relative to a second portion from a proximal starting position to a distal position along a path; a sensor module coupled to the first portion, the sensor module including a sensor, electrical contacts, and a seal; and/or a base coupled to the second portion such that the base protrudes from a distal end of the system. The base can comprise an adhesive configured to couple the sensor module to the skin. The moving of the first portion to the distal position can couple the sensor module to the base. The sensor can be an analyte sensor; a glucose sensor; any sensor described herein or incorporated by reference; and/or any other suitable sensor.

[0008] In some embodiments (i.e., optional and independently combinable with any of the aspects and embodiments identified herein), the sensor module can include a sensor module housing. The sensor module housing can include a first flex arm.

[0009] In some embodiments (i.e., optional and independently combinable with any of the aspects and embodiments identified herein), the sensor can be located within the second portion while the base protrudes from the distal end of the system such that the system is configured to couple the sensor to the base via moving the first portion distally relative to the second portion.

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[0010] In several embodiments (i.e., optional and independently combinable with any of the aspects and embodiments identified herein), the sensor can be coupled to the sensor module while the first portion is located in the proximal starting position.

[0011] In some embodiments, a needle is coupled to the first portion (of the telescoping assembly) such that the sensor and the needle move distally relative to the base and relative to the second portion. The system can comprise a needle release mechanism configured to retract the needle proximally.

[0012] In several embodiments, the base comprises a distal protrusion having a first hole. The distal protrusion can be configured to reduce a resistance of the skin to piercing. The sensor can pass through the first hole of the distal protrusion.

[0013] In some embodiments, a needle having a slot passes through the first hole of the distal protrusion. A portion of the sensor can be located in the slot such that the needle is configured to move distally relative to the base without dislodging the portion of the sensor from the slot.

[0014] In several embodiments, the distal protrusion is convex such that the distal protrusion is configured to tension the skin while the first portion moves distally relative to the second portion to prepare the skin for piercing. The distal protrusion can be shaped like a dome.

[0015] In some embodiments, the adhesive comprises a second hole. The distal protrusion can be located at least partially within the second hole such that the distal protrusion can tension at least a portion of the skin beneath the second hole.

[0016] In several embodiments, the adhesive covers at least a majority of the distal protrusion. The adhesive can cover at zero percent, at least 30 percent, at least 70 percent, and/or less than 80 percent of the distal protrusion. The distal protrusion can protrude at least 0.5 millimeters, less than 3 millimeters, and/or less than 5 millimeters.

[0017] In some embodiments, a sensor module is coupled to the first portion and is located at least 3 millimeters and/or at least 5 millimeters from the base while the first portion is in the proximal starting position. The system can be configured such that moving the first portion to the distal position couples the sensor module to the base.

[0018] In several embodiments, the sensor is already coupled to the sensor module while the first portion is located in the proximal starting position. For example, the sensor can be coupled to the sensor module at the factory (e.g., prior to the user opening a sterile barrier). The

sensor can be located within the second portion while the base protrudes from the distal end of the system.

[0019] In some embodiments, the sensor is coupled to a sensor module. During a first portion of the path, the sensor module can be immobile relative to the first portion, and the base can be immobile relative to the second portion. During a second portion of the path, the system can be configured to move the first portion distally relative to the second portion to move the sensor module towards the base, couple the sensor module to the base, and/or enable the coupled sensor module and the base to detach from the telescoping assembly.

[0020] In several embodiments, a sensor module is coupled to the sensor. The system comprises a vertical central axis oriented from a proximal end to the distal end of the system. The sensor module can comprise a first flex arm that is oriented horizontally and is coupled to the base. The first flex arm can extend from an outer perimeter of the sensor module.

[0021] In some embodiments, the base comprises a first proximal protrusion coupled to the first flex arm to couple the sensor module to the base. A first horizontal locking protrusion can be coupled to an end portion of the first flexible arm. A second horizontal locking protrusion can be coupled to the first proximal protrusion of the base. The first horizontal locking protrusion can be located distally under the second horizontal locking protrusion to secure the sensor module to the base. The system can be configured such that moving the first portion of the telescoping assembly to the distal position causes the first flex arm to bend to enable the first horizontal locking protrusion to move distally relative to the second horizontal locking protrusion.

[0022] In several embodiments, the base comprises a second proximal protrusion coupled to a second flex arm of the sensor module. The first flex arm can be located on an opposite side of the sensor module relative to the second flex arm.

[0023] In some embodiments, a sensor module is coupled to the sensor. The system can comprise a vertical central axis oriented from a proximal end to the distal end of the system. The base can comprise a first flex arm that is oriented horizontally and is coupled to the sensor module. The sensor module can comprise a first distal protrusion coupled to the first flex arm to couple the sensor module to the base.

[0024] In several embodiments, a first horizontal locking protrusion is coupled to an end portion of the first flexible arm, a second horizontal locking protrusion is coupled to the first

distal protrusion of the sensor module, and the second horizontal locking protrusion is located distally under the first horizontal locking protrusion to secure the sensor module to the base. The system can be configured such that moving the first portion of the telescoping assembly to the distal position causes the first flex arm to bend to enable the second horizontal locking protrusion to move distally relative to the first horizontal locking protrusion.

[0025] In some embodiments, the sensor module comprises a second distal protrusion coupled to a second flex arm of the base. The first distal protrusion can be located on an opposite side of the sensor module relative to the second distal protrusion.

[0026] In several embodiments, a sensor module is coupled to the sensor. The first portion can comprise a first flex arm and a second flex arm that protrude distally and latch onto the sensor module to releasably secure the sensor module to the first portion while the first portion is in the proximal starting position. The sensor module can be located remotely from the base while the first portion is in the proximal starting position (e.g., such that the sensor module does not touch the base).

[0027] In some embodiments, the sensor module is located within the second portion while the base protrudes from the distal end of the system such that the system is configured to couple the sensor module to the base via moving the first portion distally relative to the second portion.

[0028] In several embodiments, the system comprises a vertical central axis oriented from a proximal end to the distal end of the system. The first and second flex arms of the first portion can secure the sensor module to the first portion such that the sensor module is releasably coupled to the first portion with a first vertical holding strength. The sensor module can comprise a third flex arm coupled with a first proximal protrusion of the base such that the sensor module is coupled to the base with a second vertical holding strength.

[0029] In some embodiments, the second vertical holding strength is greater than the first vertical holding strength such that continuing to push the first portion distally once the sensor module is coupled to the base overcomes the first and second flex arms of the first portion to detach the sensor module from the first portion. The third flex arm can extend from an outer perimeter of the sensor module.

[0030] In several embodiments, the base protrudes from the distal end of the system while the first portion of the telescoping assembly is located in the proximal starting position and

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the sensor is located remotely relative to the base such that the system is configured to couple the sensor to the base via moving the first portion distally relative to the second portion. The base can comprise a first radial protrusion releasably coupled with a first vertical holding strength to a second radial protrusion of the second portion of the telescoping assembly.

[0031] In some embodiments, the first radial protrusion protrudes inward and the second radial protrusion protrudes outward. The system can be configured such that moving the first portion to the distal position moves the second radial protrusion relative to the first radial protrusion to detach the base from the telescoping assembly.

[0032] In several embodiments, the first portion of the telescoping assembly comprises a first arm that protrudes distally, the second portion of the telescoping assembly comprises a second flex arm that protrudes distally, and the system is configured such that moving the first portion from the proximal starting position to the distal position along the path causes the first arm to deflect the second flex arm and thereby detach the second flex arm from the base to enable the base to decouple from the telescoping assembly. When the first portion is in the proximal starting position, the first arm of the first portion can be at least partially vertically aligned with the second flex arm of the second portion to enable the first arm to deflect the second flex arm as the first portion is moved to the distal position.

[0033] In some embodiments, when the first portion is in the proximal starting position, at least a section of the first arm is located directly over the second flex arm to enable the first arm to deflect the second flex arm as the first portion is moved to the distal position.

[0034] In several embodiments, the second flex arm comprises a first horizontal protrusion, and the base comprises a second horizontal protrusion latched with the first horizontal protrusion to couple the base to the second portion of the telescoping assembly. The first arm of the first portion can deflect the second flex arm of the second portion to unlatch the base from the second portion of the telescoping assembly.

[0035] In some embodiments, the system is configured to couple the sensor to the base at a first position, and the system is configured to detach the base from the telescoping assembly at a second position that is distal relative to the first position.

[0036] In several embodiments, a third flex arm couples the sensor to the base at a first position, the second flex arm detaches from the base at a second position, and the second

position is distal relative to the first position such that the system is configured to secure the base to the telescoping assembly until after the sensor is secured to the base.

[0037] In some embodiments, the base protrudes from the distal end of the system while the first portion of the telescoping assembly is located in the proximal starting position and the sensor is located remotely relative to the base. The system can further comprise a spring configured to retract a needle. The needle can be configured to facilitate inserting the sensor into the skin. When the first portion is in the proximal starting position, the spring can be in a first compressed state. The system can be configured such that moving the first portion distally from the proximal starting position further increases a compression of the spring. The first compressed state places the first and second portions in tension.

[0038] In several embodiments, a system is configured to apply an on-skin sensor assembly to the skin of a host (i.e., a person). The system can include a telescoping assembly having a first portion configured to move distally relative to a second portion from a proximal starting position to a distal position along a path; a sensor coupled to the first portion; and/or a latch configurable to impede a needle from moving proximally relative to the first portion. The sensor can be an analyte sensor; a glucose sensor; any sensor described herein or incorporated by reference; and/or any other suitable sensor.

[0039] In some embodiments, the first portion is releasably secured in the proximal starting position by a securing mechanism that impedes moving the first portion distally relative to the second portion. The system can be configured such that prior to reaching the distal position, moving the first portion distally relative to the second portion releases the latch thereby causing the needle to retract proximally into the system. The system can be configured such that moving the first portion distally relative to the second portion (e.g., moving the first portion to the distal position) releases the latch thereby causing the needle to retract proximally into the system. The securing mechanism can be an interference between the first portion and the second portion of the telescoping assembly.

[0040] In several embodiments, a first force profile is measured along the path. The first force profile can comprise a first magnitude coinciding with overcoming the securing mechanism; a third magnitude coinciding with releasing the latch; and a second magnitude coinciding with an intermediate portion of the path that is distal relative to overcoming the securing mechanism and proximal relative to releasing the latch.

[0041] In some embodiments, the second magnitude is less than the first and third magnitudes such that the system is configured to promote needle acceleration during the intermediate portion of the path to enable a suitable needle speed (e.g., a sufficiently high needle speed) at a time the needle first pierces the skin.

[0042] In several embodiments, the first magnitude is at least 100 percent greater than the second magnitude. The first magnitude can be greater than the third magnitude such that the system is configured to impede initiating a sensor insertion cycle unless a user is applying enough force to release the latch. The first magnitude can be at least 50 percent greater than the third magnitude.

[0043] In some embodiments, an intermediate portion of the path is distal relative to overcoming the securing mechanism and proximal relative to releasing the latch. The system can further comprise a second force profile coinciding with the intermediate portion of the path. A proximal millimeter of the second force profile can comprise a lower average force than a distal millimeter of the second force profile in response to compressing a spring configured to enable the system to retract the needle into the telescoping assembly.

[0044] In several embodiments, a first force profile is measured along the path. The first force profile can comprise a first average magnitude coinciding with moving distally past a proximal half of the securing mechanism and a second average magnitude coinciding with moving distally past a distal half of the securing mechanism. The first average magnitude can be greater than the second average magnitude such that the system is configured to impede initiating a sensor insertion cycle unless a user is applying enough force to complete the sensor insertion cycle (e.g., drive the needle and/or the sensor to the intended insertion depth).

[0045] In some embodiments, a first force peak (coinciding with moving distally past the proximal half of the securing mechanism) is at least 25 percent higher than the second average magnitude.

[0046] In several embodiments, a first force profile is measured along the path. The first force profile can comprise a first magnitude coinciding with overcoming the securing mechanism and a subsequent magnitude coinciding with terminating the securing mechanism. The first magnitude can comprise a proximal vector and the subsequent magnitude can comprise a distal vector.

[0047] In some embodiments, the securing mechanism can comprise a radially outward protrusion extending from the first portion. The radially outward protrusion can be located proximally relative to a proximal end of the second portion while the telescoping assembly is in the proximal starting position. The radially outward protrusion can be configured to cause the second portion to deform elliptically to enable the first portion to move distally relative to the second portion.

[0048] In several embodiments, the securing mechanism comprises a radially outward protrusion of the first portion that interferes with a radially inward protrusion of the second portion such that the securing mechanism is configured to cause the second portion to deform elliptically to enable the first portion to move distally relative to the second portion.

[0049] In some embodiments, the needle is retractably coupled to the first portion by a needle holder configured to resist distal movement of the first portion relative to the second portion. The securing mechanism can comprise a flexible arm of the second portion. The flexible arm can be releasably coupled to the needle holder to releasably secure the first portion to the second portion in the proximal starting position.

[0050] In several embodiments, the securing mechanism comprises a frangible coupling between the first portion and the second portion while the first portion is in the proximal starting position. The system can be configured such that moving the first portion to the distal position breaks the frangible coupling.

[0051] In some embodiments, the securing mechanism comprises a magnet that releasably couples the first portion to the second portion while the first portion is in the proximal starting position. The magnet can be attracted to a metal element coupled to the first portion or the second portion of the telescoping assembly.

[0052] In several embodiments, an electric motor drives the first portion distally relative to the second portion. The electric motor can be configured to move the needle in the skin.

[0053] In some embodiments, an on-skin sensor system is configured for transcutaneous glucose monitoring of a host. The system can comprise a sensor module housing, in which the sensor module housing can include a first flex arm; a sensor having a first section configured for subcutaneous sensing and a second section mechanically coupled to the sensor module housing; an electrical interconnect mechanically coupled to the sensor module housing and electrically coupled to the sensor; and/or a base coupled to the first flex arm of the sensor module housing.

The base can have an adhesive configured to couple the base to the skin of the host. The sensor can be an analyte sensor; a glucose sensor; any sensor described herein or incorporated by reference; and/or any other suitable sensor.

[0054] In several embodiments, the electrical interconnect comprises a spring. The spring can comprise a conical portion and/or a helical portion.

[0055] In some embodiments, the sensor module housing comprises at least two proximal protrusions located around a perimeter of the spring. The proximal protrusions can be configured to help orient the spring. A segment of the sensor can be located between the proximal protrusions.

[0056] In several embodiments, the sensor module housing is mechanically coupled to a base having an adhesive configured to couple the base to skin of the host.

[0057] In some embodiments, the proximal protrusions orient the spring such that coupling an electronics unit to the base presses the spring against a first electrical contact of the electronics unit and a second electrical contact of the sensor to electrically couple the sensor to the electronics unit.

[0058] In several embodiments, the sensor module housing comprises a first flex arm that is oriented horizontally and is coupled to the base. The first flex arm can extend from an outer perimeter of the sensor module housing. The base can comprise a first proximal protrusion coupled to the first flex arm to couple the sensor module housing to the base.

[0059] In some embodiments, the electrical interconnect comprises a leaf spring, which can include one metal layer or multiple metal layers. The leaf spring can be a cantilever spring.

[0060] In some embodiments, the sensor module housing comprises a proximal protrusion having a channel in which at least a portion of the second section of the sensor is located. The channel can position a first area of the sensor such that the first area is electrically coupled to the leaf spring.

[0061] In some embodiments, the leaf spring arcs away from the first area and protrudes proximally to electrically couple with an electronics unit. At least a portion of the leaf spring can form a "W" shape. At least a portion of the leaf spring forms a "C" shape.

[0062] In several embodiments, the leaf spring bends around the proximal protrusion. The leaf spring can bend at least 120 degrees and/or at least 160 degrees around the proximal

protrusion. The leaf spring can protrude proximally to electrically couple with an electronics unit.

[0063] In some embodiments, a seal is configured to impede fluid ingress to the leaf spring. The sensor module housing can be mechanically coupled to a base. The base can have an adhesive configured to couple the base to skin of the host.

[0064] In several embodiments, the leaf spring is oriented such that coupling an electronics unit to the base presses the leaf spring against a first electrical contact of the electronics unit and against a second electrical contact of the sensor to electrically couple the sensor to the electronics unit. A proximal height of the seal can be greater than a proximal height of the leaf spring such that the electronics unit contacts the seal prior to contacting the leaf spring.

[0065] In some embodiments, the sensor module housing comprises a first flex arm that is oriented horizontally and is coupled to the base. The first flex arm can extend from an outer perimeter of the sensor module housing. The base can comprise a first proximal protrusion coupled to the first flex arm to couple the sensor module housing to the base.

[0066] In several embodiments, the sensor module housing comprises a channel in which at least a portion of the second section of the sensor is located. A distal portion of the leaf spring can be located in the channel such that a proximal portion of the leaf spring protrudes proximally out the channel. The sensor module housing can comprise a groove that intersects the channel. The leaf spring can comprise a tab located in the groove to impede rotation of the leaf spring.

[0067] In some embodiments, the sensor module housing is mechanically coupled to a base that has an adhesive configured to couple the base to skin of the host. The sensor module housing can comprise a first flex arm that is oriented horizontally and is coupled to the base. The first flex arm can extend from an outer perimeter of the sensor module housing. The base can comprises a first proximal protrusion coupled to the first flex arm to couple the sensor module housing to the base.

[0068] In several embodiments, electrical interconnects (such as springs or other types of interconnects) comprises a resistance of less than 100 ohms and/or less than 5 ohms. Electrical interconnects can comprise a compression force of less than one pound over an active compression range.

[0069] In some embodiments, electrical interconnects may require a compression force of less than one pound to compress the spring 20 percent from a relaxed position, which is a substantially uncompressed position. In some embodiments, electrical interconnects may require a compression force of less than one pound to compress the spring 25 percent from a relaxed position, which is a substantially uncompressed position. In some embodiments, electrical interconnects may require a compression force of less than one pound to compress the spring 30 percent from a relaxed position, which is a substantially uncompressed position. In some embodiments, electrical interconnects may require a compression force of less than one pound to compress the spring 50 percent from a relaxed position, which is a substantially uncompressed position.

[0070] In several embodiments, the spring is configured such that compressing the spring 25 percent from a relaxed position requires a force of at least 0.05 pounds and less than 0.5 pounds, and requires moving an end of the spring at least 0.1 millimeter and less than 1.1 millimeter.

[0071] In some embodiments, a system for applying an on-skin sensor assembly to a skin of a host comprises a telescoping assembly having a first portion configured to move distally relative to a second portion from a proximal starting position to a distal position along a path; a sensor coupled to the first portion; and a base comprising adhesive configured to couple the sensor to the skin. The telescoping assembly can further comprise a third portion configured to move distally relative to the second portion.

[0072] In some embodiments, a first spring is positioned between the third portion and the second portion such that moving the third portion distally relative to the second portion compresses the first spring. In the proximal starting position of the telescoping assembly, the first portion can be locked to the second portion. The system can be configured such that moving the third portion distally relative to the second portion unlocks the first portion from the second portion.

[0073] In several embodiments, a first proximal protrusion having a first hook passes through a first hole in the second portion to lock the first portion to the second portion. The third portion can comprise a first distal protrusion. The system can be configured such that moving the third portion distally relative to the second portion engages a ramp to bend the first proximal protrusion to unlock the first portion from the second portion.

[0074] In some embodiments, the sensor is located within the second portion while the base protrudes from the distal end of the system such that the system is configured to couple the sensor to the base by moving the first portion distally relative to the second portion.

[0075] In several embodiments, a sensor module is coupled to a distal portion of the first portion such that moving the first portion to the distal position couples the sensor module to the base. The sensor can be coupled to the sensor module while the first portion is located in the proximal starting position.

[0076] In some embodiments, the system is configured such that moving the third portion distally relative to the second portion unlocks the first portion from the second portion and locks the third portion to the second portion.

[0077] In several embodiments, the system comprises a first protrusion that couples with a hole of at least one of the second portion and the third portion to lock the third portion to the second portion.

[0078] In some embodiments, the system comprises a second protrusion that couples with a hole of at least one of the first portion and the second portion to lock the first portion to the second portion in response to moving the first portion distally relative to the second portion.

[0079] In several embodiments, a first spring is positioned between the third portion and the second portion such that moving the third portion distally relative to the second portion compresses the first spring and unlocks the first portion from the second portion, which enables the compressed first spring to push the first portion distally relative to the second portion, which pushes at least a portion of the sensor out of the distal end of the system and triggers a needle retraction mechanism to enable a second spring to retract a needle.

[0080] In some embodiments, a system for applying an on-skin assembly to a skin of a host is provided. Advantageously, the system includes a sensor inserter assembly having a needle assembly, a sensor module, a base, an actuation member, and a retraction member, the sensor inserter assembly having an initial configuration in which at least the sensor module is disposed in a proximal starting position, the sensor inserter assembly further having a deployed configuration in which at least the sensor module and the base are disposed at a distal applied position. Preferably, the actuation member is configured to, once activated, cause the needle assembly to move a proximal starting position to a distal insertion position, and the retraction

member is configured to, once activated, cause the needle assembly to move from the distal insertion position to a proximal retracted position.

[0081] The sensor module may comprise a sensor and a plurality of electrical contacts. In the initial configuration, the sensor can be electrically coupled to at least one of the electrical contacts. Optionally, in the initial configuration, the actuation member is in an unenergized state. In some embodiments, the actuation member can be configured to be energized by a user before being activated. In alternative embodiments, in the initial configuration, the actuation member is in an energized state.

[0082] In several embodiments the actuation member can include a spring. In an initial configuration, the spring can be in an unstressed state. In alternative embodiments, in the initial configuration, the spring is in a compressed state.

[0083] In some embodiments, the sensor inserter assembly may include a first portion and a second portion, the first portion being fixed, at least in an axial direction, with respect to the second portion at least when the sensor inserter assembly is in the initial configuration, the first portion being movable in at least a distal direction with respect to the second portion after activation of the actuation member. The first portion may be operatively coupled to the needle assembly so as to secure the needle assembly in the proximal starting position before activation of the actuation member and to urge the needle assembly toward the distal insertion position after activation of the actuation member.

[0084] In several embodiments, the retraction member is in an unenergized state when in the initial configuration. Advantageously, the retraction member is configured to be energized by the movement of the needle assembly from the proximal starting position to the distal insertion position. In the initial configuration, the retraction member may be in an energized state.

[0085] In still other embodiments, the retraction member comprises a spring. The spring may be integrally formed with the needle assembly. The spring may be operatively coupled to the needle assembly. In the initial configuration, the spring may be in an unstressed state. In other embodiments, in the initial configuration, the spring is in compression.

[0086] In some aspects, in the second configuration, the spring is in compression. In still other embodiments, in the second configuration, the spring is in tension.

[0087] In some embodiments, the sensor inserter assembly can further include a third portion, the third portion being operatively coupled to the first portion. The actuation member may be integrally formed with the third portion in certain embodiments. Optionally, the actuation member is operatively coupled to the third portion.

[0088] In some embodiments, the sensor inserter assembly includes interengaging structures configured to prevent movement of the first portion in the distal direction relative to the second portion until the interengaging structures are decoupled. Advantageously, the decoupling of the interengaging structures may activate the actuation member. In other embodiments, the interengaging structures may include a proximally extending tab of the first portion and a receptacle of the second portion configured to receive the proximally extending tab. Optionally, the sensor inserter assembly can include a decoupling member configured to decouple the interengaging structures. The decoupling member may have a distally extending tab of the third portion.

[0089] In yet other embodiments, the sensor inserter assembly can include interengaging structures configured to prevent proximal movement of the third portion with respect to the first portion. These interengaging structures may include a distally-extending latch of the third portion and a ledge of the first portion configured to engage the distally-extending latch.

[0090] In certain embodiments, the sensor inserter assembly can include interengaging structures configured to prevent proximal movement of the needle assembly at least when the needle assembly is in the distal insertion position. The interengaging structures can have radially-extending release features of the needle assembly and an inner surface of the first portion configured to compress the release features. Optionally, the sensor inserter assembly includes a decoupling member configured to disengage the interengaging structures of the first portion and the needle assembly. The decoupling member may include an inner surface of the second portion configured to further compress the release features. Advantageously, the system may further include a trigger member configured to activate the actuation member. The trigger member may be operatively coupled to the third portion. The trigger member may be integrally formed with the third portion. The trigger member may include a proximally-extending button. Alternatively, the trigger member may include a radially-extending button. The trigger member may be configured to decouple the interengaging structure of the first portion and the third portion.

[0091] In some embodiments, the system may further include a releasable locking member configured to prevent activation of the actuation member until the locking member is released. The releasable locking member may be configured to prevent proximal movement of the third portion with respect to the first portion until the locking member is released. The releasable locking member may include a proximally-extending tab of the first portion and a latch feature of the third portion configured to receive the proximally-extending tab. Advantageously, the releasable locking member is configured to prevent energizing of the sensor inserter assembly. In other aspects, the releasable locking member is configured to prevent energizing of the actuation member.

[0092] Embodiments may further include a system for applying an on-skin component to a skin of a host, the system may include a sensor inserter assembly having an on-skin component being movable in at least a distal direction from a proximal position to a distal position, a first securing feature configured to releasably secure the on-skin component in the proximal position, a second securing feature configured to secure the on-skin component in the distal position, and a first resistance configured to prevent movement of the on-skin component in a proximal direction at least when the on-skin component is in the distal position.

[0093] The first resistance feature can be configured to prevent movement of the on-skin component in a proximal direction when the on-skin component is secured in the distal position. In some embodiments, the first securing feature is configured to releasably secure the on-skin component to a needle assembly. The on-skin component may have a sensor module. The sensor module may include a sensor and a plurality of electrical contacts. Optionally, the sensor is electrically coupled to at least one of the electrical contacts, at least when the sensor inserter assembly is in the first configuration.

[0094] In some embodiments, the on-skin component comprises a base. The on-skin component may include a transmitter. The second securing feature can be configured to secure the on-skin component to a second on-skin component.

[0095] In other embodiments, the sensor inserter assembly includes at least one distally-extending leg, and wherein the first securing feature comprises an adhesive disposed on a distally-facing surface of the leg. The sensor inserter assembly may include at least one distally-extending member, and wherein the first securing feature comprises a surface of the distally-extending member configured to frictionally engage with a corresponding structure of the on-

skin component. The corresponding structure of the on-skin component may include an elastomeric member. Optionally, the distally-extending member includes at least one leg of the sensor inserter assembly. The distally-extending member may include a needle.

[0096] In some embodiments of the system, the second securing feature includes an adhesive disposed on a distally-facing surface of the on-skin component. The second securing feature may have an elastomeric member configured to receive the on-skin component.

[0097] In other embodiments, the first resistance feature includes a distally-facing surface of the sensor inserter assembly. The first resistance feature may be distal to an adhesive disposed on a distally-facing surface of the on-skin component.

[0098] The system may further include a pusher configured to move the on-skin component from the proximal position to the distal position. Optionally, the system can further include a decoupling feature configured to decouple the pusher from the on-skin component at least after the on-skin component is in the distal position. The decoupling feature may have a frangible portion of the pusher. Optionally, the decoupling feature comprises a frangible portion of the on-skin component.

[0099] The system may further comprise a sensor assembly configured to couple with the on-skin component, wherein a third securing feature is configured to releasably secure the sensor assembly in a proximal position, and wherein a fourth securing feature is configured to secure the sensor assembly to the on-skin component.

[0100] Any of the features of each embodiment is applicable to all aspects and embodiments identified herein. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0101] These and other features, aspects, and advantages are described below with reference to the drawings, which are intended to illustrate, but not to limit, the invention. In the

drawings, like reference characters denote corresponding features consistently throughout similar embodiments.

[0102] Figure 1 illustrates a schematic view of a continuous analyte sensor system, according to some embodiments.

[0103] Figure 2 illustrates a perspective view of an applicator system, according to some embodiments.

[0104] Figure 3 illustrates a cross-sectional side view of the system from Figure 2, according to some embodiments.

[0105] Figure 4 illustrates a perspective view of an on-skin sensor assembly, according to some embodiments.

[0106] Figures 5 and 6 illustrate perspective views of a transmitter coupled to a base via mechanical interlocks, according to some embodiments.

[0107] Figures 7-11 illustrate cross-sectional side views of the applicator system from Figure 3, according to some embodiments.

[0108] Figure 12A illustrates a cross-sectional side view of a portion of the applicator system from Figure 3, according to some embodiments.

[0109] Figure 12B illustrates a cross-sectional side view of a base that can be used with the applicator system shown in Figure 3, according to some embodiments.

[0110] Figure 13 illustrates a perspective view of a portion of the adhesive from Figure 4, according to some embodiments.

[0111] Figure 14 illustrates a perspective view of a portion of the applicator system from Figure 3, according to some embodiments.

[0112] Figures 15 and 16 illustrate perspective views of cross sections of portions of the system shown in Figure 7, according to some embodiments.

[0113] Figure 17 illustrates a cross-sectional view of the first portion of the telescoping assembly from Figure 7, according to some embodiments.

[0114] Figures 18 and 19 illustrate perspective views of portions of the applicator system from Figure 7, according to some embodiments.

[0115] Figures 20 and 21 illustrate perspective views of the needle after being removed from the telescoping assembly of Figure 7, according to some embodiments.

[0116] Figure 22 illustrates a perspective view of a cover of the telescoping assembly of Figure 7, according to some embodiments.

[0117] Figure 23 illustrates a schematic view of force profiles, according to some embodiments.

[0118] Figure 24 illustrates a cross-sectional side view of a portion of an applicator system, according to some embodiments.

[0119] Figure 25 illustrates a cross-sectional side view of a portion of a securing mechanism, according to some embodiments.

[0120] Figure 26 illustrates a top view of a ring, according to some embodiments.

[0121] Figure 27 illustrates a perspective view of a securing mechanism, according to some embodiments.

[0122] Figure 28 illustrates a cross-sectional perspective view of telescoping assembly with a motor, according to some embodiments.

[0123] Figures 29 and 30 illustrate cross-sectional side views of telescoping assemblies with a motor, according to some embodiments.

[0124] Figure 31 illustrates a side view of a telescoping assembly that causes rotational movement, according to some embodiments.

[0125] Figure 32 illustrates a cross-sectional perspective view of a telescoping assembly with a downward locking feature, according to some embodiments.

[0126] Figure 33 illustrates a perspective view of an on-skin senor assembly just before the electronics unit is coupled to the base, according to some embodiments.

[0127] Figures 34 and 35 illustrate perspective views of sensor modules that have springs, according to some embodiments.

[0128] Figure 36 illustrates a cross-sectional perspective view of a portion of a sensor module, according to some embodiments.

[0129] Figure 37 illustrates a perspective view of a sensor module that has springs, according to some embodiments.

[0130] Figure 38 illustrates a cross-sectional perspective view of a portion of a sensor module, according to some embodiments.

[0131] Figure 39 illustrates a perspective view of a sensor module, according to some embodiments.

[0132] Figure 40 illustrates a cross-sectional perspective view of assembly that has an offset, according to some embodiments.

[0133] Figure 41 illustrates a side view of a sensor, according to some embodiments.

[0134] Figure 42 illustrates a bottom view of a needle, according to some embodiments.

[0135] Figure 43 illustrates a front view of a needle, according to some embodiments.

[0136] Figure 44 illustrates a cross-sectional perspective view of an applicator system, according to some embodiments.

[0137] Figure 45 illustrates a cross-sectional perspective view of a portion of an applicator system, according to some embodiments.

[0138] Figure 46 illustrates a perspective view of a portion of an applicator system, according to some embodiments.

[0139] Figure 47 illustrates a perspective view of a sensor module, according to some embodiments.

[0140] Figure 48 illustrates a cross-sectional perspective view of an applicator system, according to some embodiments.

[0141] Figure 49 illustrates a cross-sectional perspective view of a proximal portion of a telescoping assembly, according to some embodiments.

[0142] Figure 50 illustrates a perspective view of a distal portion of a telescoping assembly, according to some embodiments.

[0143] Figure 51 illustrates a perspective view of a needle with adhesive, according to some embodiments.

[0144] Figure 52 illustrates a perspective view of a needle that has two separate sides, according to some embodiments.

[0145] Figure 53 illustrates a cross-sectional top view of the needle shown in Figure 52, according to some embodiments.

[0146] Figure 54 illustrates a perspective view of a needle that has a ramp, according to some embodiments.

[0147] Figure 55 illustrates a cross-sectional top view of four needles, according to some embodiments.

[0148] Figures 56-58 illustrate cross-sectional side views of a system that is similar to the embodiment shown in Figure 7 except that the system does not include a needle, according to some embodiments.

[0149] Figure 59 illustrates a cross-sectional side view of a system that is similar to the embodiment shown in Figure 7 except for the starting position and the movement of the base, according to some embodiments.

[0150] Figure 60 illustrates a perspective view of a system having a cover, according to some embodiments.

[0151] Figures 61-63 illustrate cross-sectional perspectives views of a system that is similar to the embodiment shown in Figure 7 except that the telescoping assembly includes an extra portion, according to some embodiments.

[0152] Figure 64 illustrates a cross-sectional side view of the system shown in Figures 61-63, according to some embodiments.

[0153] Figure 65 illustrates a perspective view of portions of a sensor module, according to some embodiments.

[0154] Figure 66 illustrates a cross-sectional side view of the sensor module shown in Figure 65, according to some embodiments.

[0155] Figure 67 illustrates a perspective view of portions of a sensor module, according to some embodiments.

[0156] Figure 68 illustrates a top view of the sensor module shown in Figure 67, according to some embodiments.

[0157] Figures 69 and 70 illustrate perspective views of an electronics unit just before the electronics unit is coupled to a base, according to some embodiments.

[0158] Figure 71 illustrates a cross-sectional perspective view of an applicator system, according to some embodiments, in a resting state.

[0159] Figure 72 illustrates a cross-sectional perspective view of the applicator system of Figure 71, with the actuation member energized.

[0160] Figure 73 illustrates a rotated cross-sectional perspective view of the applicator system of Figure 72.

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[0161] Figure 74 illustrates a cross-sectional perspective view of the applicator system of Figure 71, with the actuation member activated and with the needle assembly deployed in an insertion position.

[0162] Figure 75 illustrates a cross-sectional perspective view of the applicator system of Figure 71, with the on-skin component in a deployed position and the needle assembly retracted.

[0163] Figure 76 illustrates a cross-sectional side view of another applicator system, according to some embodiments, in a resting state.

[0164] Figure 77 illustrates a cross-sectional side view of the applicator system of Figure 76, with the actuation member energized.

[0165] Figure 78 illustrates a cross-sectional side view of the applicator system of Figure 76, with the actuation member activated and with the needle assembly deployed in an insertion position.

[0166] Figure 79 illustrates a cross-sectional side view of the applicator system of Figure 76, with the on-skin component in a deployed position and the needle assembly retracted.

[0167] Figure 80 illustrates a cross-sectional side view of another applicator system, according to some embodiments, in a resting state.

[0168] Figure 81 illustrates a cross-sectional side view of the applicator system of Figure 80, with the actuation member energized.

[0169] Figure 82 illustrates a cross-sectional side view of the applicator system of Figure 80, with the actuation member activated and with the needle assembly deployed in an insertion position.

[0170] Figure 83 illustrates a cross-sectional side view of the applicator system of Figure 80, with the on-skin component in a deployed position and the needle assembly retracted.

[0171] Figure 84 illustrates a perspective view of the applicator system of Figure 80, with the first and third portions shown in cross section to better illustrate certain portions of the system, and in a resting state.

[0172] Figure 85 illustrates a perspective view of the applicator system of Figure 80, with the first and third portions shown in cross section to better illustrate certain portions of the system, and with the actuation member energized.

[0173] Figure 86 illustrates a cross-sectional side view of another applicator system, according to some embodiments, in a resting state in which the actuation member is already energized.

[0174] Figure 87 illustrates a cross-sectional side view of the applicator system of Figure 86, with the actuation member activated and with the needle assembly deployed in an insertion position.

[0175] Figure 88 illustrates a cross-sectional side view of the applicator system of Figure 86, with the on-skin component in a deployed position and the needle assembly retracted.

[0176] Figure 89 illustrates a cross-sectional side view of another applicator system, according to some embodiments, in a resting state in which the actuation member is already energized.

[0177] Figure 90 illustrates a cross-sectional side view of the applicator system of Figure 86, with the actuation member activated and with the needle assembly deployed in an insertion position.

[0178] Figure 91 illustrates a cross-sectional side view of the applicator system of Figure 86, with the on-skin component in a deployed position and the needle assembly retracted.

[0179] Figure 92 illustrates a side view of another applicator system, according to some embodiments, with a top trigger member, in a resting state.

[0180] Figure 93 illustrates a side view of the applicator system of Figure 92, after being cocked but before being triggered.

[0181] Figure 94 illustrates a cross-sectional perspective view of the applicator system of Figure 92, in a resting state.

[0182] Figure 95 illustrates a cross-sectional perspective view of the applicator system of Figure 92 while being cocked.

[0183] Figure 96 illustrates a cross-sectional perspective view of the applicator system of Figure 92, after being cocked but before being triggered.

[0184] Figure 97 illustrates a cross-sectional side view of the applicator system of Figure 96.

[0185] Figure 98 illustrates a cross-sectional side view of the applicator system of Figure 92, during triggering.

[0186] Figure 99 illustrates a cross-sectional side view of the applicator system of Figure 92, after being triggered and with the needle assembly deployed in an insertion position.

[0187] Figure 100 illustrates a cross-sectional side view of the applicator system of Figure 92, with the on-skin component in a deployed position and the needle assembly retracted.

[0188] Figure 101 illustrates a side view of another applicator system, according to some embodiments, with a side trigger member.

[0189] Figure 102 illustrates another side view of the applicator system of Figure 101, with the first and third portions shown in cross-section to illustrate the trigger mechanism.

[0190] Figure 103 illustrates a side view of another applicator system, according to some embodiments, with an integrated side trigger.

[0191] Figure 104 illustrates another side view of the applicator system of Figure 103, with the first and third portions shown in cross-section and with a portion of the second portion removed to illustrate the trigger mechanism.

[0192] Figure 105 illustrates a perspective view of another applicator system, according to some embodiments, with a safety feature.

[0193] Figure 106 illustrates a cross-sectional perspective view of a portion of the applicator system of Figure 105, with the safety feature in a locked configuration.

[0194] Figure 107 illustrates an enlarged view of the portion of the applicator system of Figure 106, with the safety feature in a locked configuration.

[0195] Figure 108 illustrates a cross-sectional perspective view of a portion of the applicator system of Figure 105, with the safety feature in a released configuration.

[0196] Figure 109 illustrates a cross-sectional perspective view of a portion of the applicator system of Figure 105, with the safety feature in a released configuration and with the third portion moved distally relative to the first portion.

[0197] Figure 110 illustrates a cross-sectional perspective view of an applicator system, according to some embodiments, in a resting and locked state, with the on-skin component secured in a proximal position.

[0198] Figure 111 illustrates a cross-sectional perspective view of the applicator system of Figure 110, with the safety feature unlocked.

[0199] Figure 112 illustrates a cross-sectional perspective view of the applicator system of Figure 110, with the actuation member energized.

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[0200] Figure 113 illustrates a cross-sectional perspective view of the applicator system of Figure 110, with the actuation member activated and with the needle assembly and on-skin component deployed in a distal position.

[0201] Figure 114 illustrates a cross-sectional perspective view of the applicator system of Figure 110, with the on-skin component in a deployed position and separated from the retracted needle assembly.

[0202] Figure 115 illustrates a perspective view of the needle assembly from the system of Figure 110, shown securing the on-skin component during deployment, with the base removed for purposes of illustration.

[0203] Figure 116 illustrates another perspective view of the needle assembly from the system of Figure 110, shown separated from the on-skin component, with the base removed for purposes of illustration.

[0204] Figure 117 illustrates a perspective view of a portion of the system of Figure 100.

[0205] Figure 118 illustrates a perspective view of the sensor module of Figure 100, before being coupled to the base.

[0206] Figure 119 illustrates a perspective view of the sensor module of Figure 100, after being coupled to the base.

[0207] Figure 120 illustrates a side view of an on-skin component and base, according to some embodiments, prior to coupling of the on-skin component to the base.

[0208] Figure 121 illustrates a perspective view of the on-skin component and base of Figure 120, prior to coupling of the on-skin component to the base.

[0209] Figure 122 illustrates a side view of the on-skin component and base of Figure 120, after coupling of the on-skin component to the base.

[0210] Figure 123 illustrates a perspective view of a portion of another applicator system, according to some embodiments, with an on-skin component coupled to a needle assembly in a proximal position.

[0211] Figure 124 illustrates a perspective view of the on-skin component and the needle assembly of Figure 123.

[0212] Figure 125 illustrates a perspective view of a portion of the applicator system shown in Figure 123, with the on-skin component separated from the needle assembly.

[0213] Figure 126 illustrates a perspective view of a portion of a securing member, shown securing an on-skin component.

[0214] Figure 127 illustrates a perspective view of a portion of the securing member of Figure 126, with the sensor module of the on-skin component shown in cross section, and illustrated with a decoupling feature of an applicator assembly, according to some embodiments.

[0215] Figure 128 illustrates a perspective view of the on-skin component of Figure 126, after decoupling of the on-skin component from the securing member.

[0216] Figure 129 illustrates a perspective view of a portion of an applicator assembly, according to some embodiments, with the second portion shown in cross section, and with a securing member shown securing an on-skin component in a proximal position.

[0217] Figure 130 illustrates a perspective view of a portion of the applicator assembly of Figure 129, shown with a portion of the securing member cut away to better illustrate the configuration of the securing member.

[0218] Figure 131 illustrates a perspective view of a portion of the applicator assembly of Figure 129, after decoupling of the on-skin component from the needle assembly, shown with portions of the on-skin component and the securing member cut away.

[0219] Figure 132 illustrates a perspective view of a portion of an applicator assembly, according to some embodiments, with the second portion shown in cross section, and with a securing member shown securing an on-skin component in a proximal position.

[0220] Figure 133 illustrates a perspective view of the needle assembly and on-skin component of Figure 132, after decoupling of the on-skin component from the needle assembly.

[0221] Figure 134 illustrates an exploded perspective view of a portion of an applicator assembly, according to some embodiments, with a securing member configured to releasably couple an on-skin component to a needle assembly.

[0222] Figure 135 illustrates a perspective view of a portion of the applicator assembly of Figure 134, with the needle assembly coupled to the on-skin component.

[0223] Figure 136 illustrates a perspective view of a portion of the applicator assembly of Figure 134, with the needle assembly decoupled from the on-skin component.

[0224] Figure 137 illustrates a perspective view of an applicator assembly, according to some embodiments, with an on-skin component releasably secured in a proximal position within the applicator assembly.

[0225] Figure 138 illustrates a perspective view of the applicator assembly of Figure 137, with the on-skin component released from securement.

[0226] Figure 139 illustrates a perspective view of the on-skin component of Figure 137, with the securing feature in a secured configuration.

[0227] Figure 140 illustrates a perspective view of the on-skin component of Figure 137, with the securing feature in a released configuration.

[0228] Figure 141 illustrates a cross-sectional perspective view of a portion of an applicator assembly, according to some embodiments, with the second and third portions shown in cross section, and showing a base coupled to an applicator.

[0229] Figure 142 illustrates a perspective view of another applicator assembly, according to some embodiments, showing a patch coupled to an applicator.

[0230] Figure 143 illustrates a perspective view of the applicator assembly of Figure 142, the patch decoupled from the applicator.

DETAILED DESCRIPTION OF CERTAIN INVENTIVE EMBODIMENTS

[0231] Although certain embodiments and examples are disclosed below, inventive subject matter extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses, and to modifications and equivalents thereof. Thus, the scope of the claims appended hereto is not limited by any of the particular embodiments described below. For example, in any method or process disclosed herein, the acts or operations of the method or process may be performed in any suitable sequence and are not necessarily limited to any particular disclosed sequence. Various operations may be described as multiple discrete operations in turn, in a manner that may be helpful in understanding certain embodiments; however, the order of description should not be construed to imply that these operations are order dependent. Additionally, the structures, systems, and/or devices described herein may be embodied as integrated components or as separate components.

[0232] For purposes of comparing various embodiments, certain aspects and advantages of these embodiments are described. Not necessarily all such aspects or advantages are achieved by any particular embodiment. Thus, for example, various embodiments may be carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other aspects or advantages as may also be taught or suggested herein.

SYSTEM INTRODUCTION

[0233] U.S. Patent Publication No. US-2013-0267811-A1, the entire contents of which are incorporated by reference herein, explains how Figure 1 is a schematic of a continuous analyte sensor system 100 attached to a host (e.g., a person). The analyte sensor system 100 communicates with other devices 110-113 (which can be located remotely from the host). A transcutaneous analyte sensor system 102 comprising an on-skin sensor assembly 600 is fastened to the skin of a host via a base (not shown), which can be a disposable housing.

[0234] The system 102 includes a transcutaneous analyte sensor 200 and an electronics unit (referred to interchangeably as "sensor electronics" or "transmitter") 500 for wirelessly transmitting analyte information to a receiver. The receiver can be located remotely relative to the system 102. In some embodiments, the receiver includes a display screen, which can display information to a person such as the host. Example receivers include computers such as smartphones, smartwatches, tablet computers, laptop computers, and desktop computers. In some embodiments, receivers can be Apple Watches, iPhones, and iPads made by Apple Inc. In still further embodiments, the system 102 can be configured for use in applying a drug delivery device, such an infusion device, to the skin of a patient. In such embodiments, the system can include a catheter instead of, or in addition to, a sensor, the catheter being connected to an infusion pump configured to deliver liquid medicines or other fluids into the patient's body. In embodiments, the catheter can be deployed into the skin in much the same manner as a sensor would be, for example as described herein.

[0235] In some embodiments, the receiver is mechanically coupled to the electronics unit 500 to enable the receiver to receive data (e.g., analyte data) from the electronics unit 500. To increase the convenience to users, in several embodiments, the receiver does not need to be mechanically coupled to the electronics unit 500 and can even receive data from the electronics unit 500 over great distances (e.g., when the receiver is many feet or even many miles from the electronics unit 500).

[0236] During use, a sensing portion of the sensor 200 can be under the host's skin and a contact portion of the sensor 200 can be electrically connected to the electronics unit 500. The electronics unit 500 can be engaged with a housing (e.g., a base) which is attached to an adhesive patch fastened to the skin of the host.

[0237] The on-skin sensor assembly 600 may be attached to the host with use of an applicator adapted to provide convenient and secure application. Such an applicator may also be used for attaching the electronics unit 500 to a base, inserting the sensor 200 through the host's skin, and/or connecting the sensor 200 to the electronics unit 500. Once the electronics unit 500 is engaged with the base and the sensor 200 has been inserted into the skin (and is connected to the electronics unit 500), the sensor assembly can detach from the applicator.

[0238] The continuous analyte sensor system 100 can include a sensor configuration that provides an output signal indicative of a concentration of an analyte. The output signal including (e.g., sensor data, such as a raw data stream, filtered data, smoothed data, and/or otherwise transformed sensor data) is sent to the receiver.

[0239] In some embodiments, the analyte sensor system 100 includes a transcutaneous glucose sensor, such as is described in U.S. Patent Publication No. US-2011-0027127-A1, the entire contents of which are hereby incorporated by reference. In some embodiments, the sensor system 100 includes a continuous glucose sensor and comprises a transcutaneous sensor (e.g., as described in U.S. Pat. No. 6,565,509, as described in U.S. Pat. No. 6,579,690, as described in U.S. Pat. No. 6,484,046). The contents of U.S. Pat. No. 6,565,509, U.S. Pat. No. 6,579,690, and U.S. Pat. No. 6,484,046 are hereby incorporated by reference in their entirety.

[0240] In several embodiments, the sensor system 100 includes a continuous glucose sensor and comprises a refillable subcutaneous sensor (e.g., as described in U.S. Pat. No. 6,512,939). In some embodiments, the sensor system 100 includes a continuous glucose sensor and comprises an intravascular sensor (e.g., as described in U.S. Pat. No. 6,477,395, as described in U.S. Pat. No. 6,424,847). The contents of U.S. Pat. No. 6,512,939, U.S. Pat. No. 6,477,395, and U.S. Pat. No. 6,424,847 are hereby incorporated by reference in their entirety.

[0241] Various signal processing techniques and glucose monitoring system embodiments suitable for use with the embodiments described herein are described in U.S. Patent Publication No. US-2005-0203360-A1 and U.S. Patent Publication No. US-2009-0192745-A1, the contents of which are hereby incorporated by reference in their entirety. The sensor can extend through a housing, which can maintain the sensor on the skin and can provide for electrical connection of the sensor to sensor electronics, which can be provided in the electronics unit 500.

[0242] In several embodiments, the sensor is formed from a wire or is in a form of a wire. A distal end of the wire can be sharpened to form a conical shape (to facilitate inserting the wire into the tissue of the host). The sensor can include an elongated conductive body, such as a bare elongated conductive core (e.g., a metal wire) or an elongated conductive core coated with one, two, three, four, five, or more layers of material, each of which may or may not be conductive. The elongated sensor may be long and thin, yet flexible and strong. For example, in some embodiments, the smallest dimension of the elongated conductive body is less than 0.1 inches, less than 0.075 inches, less than 0.05 inches, less than 0.025 inches, less than 0.01 inches, less than 0.004 inches, and/or less than 0.002 inches.

[0243] The sensor may have a circular cross section. In some embodiments, the cross section of the elongated conductive body can be ovoid, rectangular, triangular, polyhedral, star-shaped, C-shaped, T-shaped, X-shaped, Y-shaped, irregular, or the like. In some embodiments, a conductive wire electrode is employed as a core. To such an electrode, one or two additional conducting layers may be added (e.g., with intervening insulating layers provided for electrical isolation). The conductive layers can be comprised of any suitable material. In certain embodiments, it may be desirable to employ a conductive layer comprising conductive particles (i.e., particles of a conductive material) in a polymer or other binder.

[0244] In some embodiments, the materials used to form the elongated conductive body (e.g., stainless steel, titanium, tantalum, platinum, platinum-iridium, iridium, certain polymers, and/or the like) can be strong and hard, and therefore can be resistant to breakage. For example, in several embodiments, the ultimate tensile strength of the elongated conductive body is greater than 80 kPsi and less than 500 kPsi, and/or the Young's modulus of the elongated conductive body is greater than 160 GPa and less than 220 GPa. The yield strength of the elongated conductive body can be greater than 60 kPsi and less than 2200 kPsi.

[0245] The electronics unit 500 can be releasably coupled to the sensor 200. The electronics unit 500 can include electronic circuitry associated with measuring and processing the continuous analyte sensor data. The electronics unit 500 can be configured to perform algorithms associated with processing and calibration of the sensor data. For example, the electronics unit 500 can provide various aspects of the functionality of a sensor electronics module as described in U.S. Patent Publication No. US-2009-0240120-A1 and U.S. Patent Publication No. US-2012-0078071 -A1, the entire contents of which are incorporated by

reference herein. The electronics unit 500 may include hardware, firmware, and/or software that enable measurement of levels of the analyte via a glucose sensor, such as an analyte sensor 200.

[0246] For example, the electronics unit 500 can include a potentiostat, a power source for providing power to the sensor 200, signal processing components, data storage components, and a communication module (e.g., a telemetry module) for one-way or two-way data communication between the electronics unit 500 and one or more receivers, repeaters, and/or display devices, such as devices 110-113. Electronics can be affixed to a printed circuit board (PCB), or the like, and can take a variety of forms. The electronics can take the form of an integrated circuit (IC), such as an Application-Specific Integrated Circuit (ASIC), a microcontroller, and/or a processor. The electronics unit 500 may include sensor electronics that are configured to process sensor information, such as storing data, analyzing data streams, calibrating analyte sensor data, estimating analyte values, comparing estimated analyte values with time-corresponding measured analyte values, analyzing a variation of estimated analyte values, and the like. Examples of systems and methods for processing sensor analyte data are described in more detail in U.S. Pat. No. 7,310,544, U.S. Pat. No. 6,931,327, U.S. Patent Publication No. 2005-0043598-A1, U.S. Patent Publication No. 2007-0032706-A1, U.S. Patent Publication No. 2007-0016381-A1, U.S. Patent Publication No. 2008-0033254-A1, U.S. Patent Publication No. 2005-0203360-A1, U.S. Patent Publication No. 2005-0154271-A1, U.S. Patent Publication No. 2005-0192557-A1, U.S. Patent Publication No. 2006-0222566-A1, U.S. Patent Publication No. 2007-0203966-A1 and U.S. Patent Publication No. 2007-0208245-A1, the contents of which are hereby incorporated by reference in their entirety.

[0247] One or more repeaters, receivers and/or display devices, such as a key fob repeater 110, a medical device receiver 111 (e.g., an insulin delivery device and/or a dedicated glucose sensor receiver), a smartphone 112, a portable computer 113, and the like can be communicatively coupled to the electronics unit 500 (e.g., to receive data from the electronics unit 500). The electronics unit 500 can also be referred to as a transmitter. In some embodiments, the devices 110-113 transmit data to the electronics unit 500. The sensor data can be transmitted from the sensor electronics unit 500 to one or more of the key fob repeater 110, the medical device receiver 111, the smartphone 112, the portable computer 113, and the like. In some embodiments, analyte values are displayed on a display device.

[0248] The electronics unit 500 may communicate with the devices 110-113, and/or any number of additional devices, via any suitable communication protocol. Example communication protocols include radio frequency; Bluetooth; universal serial bus; any of the wireless local area network (WLAN) communication standards, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols; ZigBee; wireless (e.g., cellular) telecommunication; paging network communication; magnetic induction; satellite data communication; and/or a proprietary communication protocol.

[0249] Additional sensor information is described in U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201. The entire contents of U.S. Patent No. 7,497,827 and U.S. Patent No. 8,828,201 are incorporated by reference herein.

[0250] Any sensor shown or described herein can be an analyte sensor; a glucose sensor; and/or any other suitable sensor. A sensor described in the context of any embodiment can be any sensor described herein or incorporated by reference. Thus, for example, the sensor 138 shown in Figure 7 can be an analyte sensor; a glucose sensor; any sensor described herein; and any sensor incorporated by reference. Sensors shown or described herein can be configured to sense, measure, detect, and/or interact with any analyte.

[0251] As used herein, the term "analyte" is a broad term, and is to be given its ordinary and customary meaning to a person of ordinary skill in the art (and is not to be limited to a special or customized meaning), and refers without limitation to a substance or chemical constituent in a biological fluid (for example, blood, interstitial fluid, cerebral spinal fluid, lymph fluid, urine, sweat, saliva, etc.) that can be analyzed. Analytes can include naturally occurring substances, artificial substances, metabolites, or reaction products.

[0252] In some embodiments, the analyte for measurement by the sensing regions, devices, systems, and methods is glucose. However, other analytes are contemplated as well, including, but not limited to ketone bodies; Acetyl Co A; acarboxyprothrombin; acylcarnitine; adenine phosphoribosyl transferase; adenosine deaminase; albumin; alpha-fetoprotein; amino acid profiles (arginine (Krebs cycle), histidine/urocanic acid, homocysteine, phenylalanine/tyrosine, tryptophan); andrenostenedione; antipyrine; arabinitol enantiomers; arginase; benzoylecgonine (cocaine); biotinidase; biopterin; c-reactive protein; carnitine; carnosinase; CD4; ceruloplasmin; chenodeoxycholic acid; chloroquine; cholesterol; cholinesterase; cortisol; testosterone; choline; creatine kinase; creatine kinase MM isoenzyme;

cyclosporin A; d-penicillamine; de-ethylchloroquine; dehydroepiandrosterone sulfate; DNA (acetylator polymorphism, alcohol dehydrogenase, alpha 1-antitrypsin, cystic fibrosis, Duchenne/Becker muscular dystrophy, glucose-6-phosphate dehydrogenase, hemoglobin A, hemoglobin S, hemoglobin C, hemoglobin D, hemoglobin E, hemoglobin F, D-Punjab, beta-thalassemia, hepatitis B virus, HCMV, HIV-1, HTLV-1, Leber hereditary optic neuropathy, MCAD, RNA, PKU, Plasmodium vivax, sexual differentiation, 21-deoxycortisol); desbutylhalofantrine; dihydropteridine reductase; diptheria/tetanus antitoxin; erythrocyte arginase; erythrocyte protoporphyrin; esterase D; fatty acids/acylglycines; triglycerides; glycerol; free ß-human chorionic gonadotropin; free erythrocyte porphyrin; free thyroxine (FT4); free tri-iodothyronine (FT3); fumarylacetoacetase; galactose/gal-1-phosphate; galactose-1-phosphate uridyltransferase; gentamicin; glucose-6-phosphate dehydrogenase; glutathione; glutathione perioxidase; glycocholic acid; glycosylated hemoglobin; halofantrine; hemoglobin variants; hexosaminidase A; human erythrocyte carbonic anhydrase I; 17-alpha-hydroxyprogesterone; hypoxanthine phosphoribosyl transferase; immunoreactive trypsin; lactate; lead; lipoproteins ((a), B/A-1, ß); lysozyme; mefloquine; netilmicin; phenobarbitone; phenytoin; phytanic/pristanic acid; progesterone; prolactin; prolidase; purine nucleoside phosphorylase; quinine; reverse tri-iodothyronine (rT3); selenium; serum pancreatic lipase; sissomicin; somatomedin C; specific antibodies (adenovirus, anti-nuclear antibody, anti-zeta antibody, arbovirus, Aujeszky's disease virus, dengue virus, Dracunculus medinensis, Echinococcus granulosus, Entamoeba histolytica, enterovirus, Giardia duodenalisa, Helicobacter pylori, hepatitis B virus, herpes virus, HIV-1, IgE (atopic disease), influenza virus, Leishmania donovani, leptospira, measles/mumps/rubella, Mycobacterium leprae, Mycoplasma pneumoniae, Myoglobin, Onchocerca volvulus, parainfluenza virus, Plasmodium falciparum, poliovirus, Pseudomonas aeruginosa, respiratory syncytial virus, rickettsia (scrub typhus), Schistosoma mansoni, Toxoplasma gondii, Trepenoma pallidium, Trypanosoma cruzi/rangeli, vesicular stomatis virus, Wuchereria bancrofti, yellow fever virus); specific antigens (hepatitis B virus, HIV-1); acetone (e.g., succinylacetone); acetoacetic acid; sulfadoxine; theophylline; thyrotropin (TSH); thyroxine (T4); thyroxine-binding globulin; trace elements; transferrin; UDP-galactose-4-epimerase; urea; uroporphyrinogen I synthase; vitamin A; white blood cells; and zinc protoporphyrin.

[0253] Salts, sugar, protein, fat, vitamins, and hormones naturally occurring in blood or interstitial fluids can also constitute analytes in certain embodiments. The analyte can be

naturally present in the biological fluid or endogenous, for example, a metabolic product, a hormone, an antigen, an antibody, and the like. Alternatively, the analyte can be introduced into the body or exogenous, for example, a contrast agent for imaging, a radioisotope, a chemical agent, a fluorocarbon-based synthetic blood, or a drug or pharmaceutical composition, including but not limited to insulin; glucagon; ethanol; cannabis (marijuana, tetrahydrocannabinol, hashish); inhalants (nitrous oxide, amyl nitrite, butyl nitrite, chlorohydrocarbons, hydrocarbons); cocaine (crack cocaine); stimulants (amphetamines, methamphetamines, Ritalin, Cylert, Preludin, Didrex, PreState, Voranil, Sandrex, Plegine); depressants (barbiturates, methaqualone, tranquilizers such as Valium, Librium, Miltown, Serax, Equanil, Tranxene); hallucinogens (phencyclidine, lysergic acid, mescaline, peyote, psilocybin); narcotics (heroin, codeine, morphine, opium, meperidine, Percocet, Percodan, Tussionex, Fentanyl, Darvon, Talwin, Lomotil); designer drugs (analogs of fentanyl, meperidine, amphetamines, methamphetamines, and phencyclidine, for example, Ecstasy); anabolic steroids; and nicotine. The metabolic products of drugs and pharmaceutical compositions are also contemplated analytes. Analytes such as neurochemicals and other chemicals generated within the body can also be analyzed, such as, for example, ascorbic acid, uric acid, dopamine, noradrenaline, 3-methoxytyramine (3MT), 3,4-dihydroxyphenylacetic acid (DOPAC), homovanillic acid (HVA), 5-hydroxytryptamine (5HT), 5-hydroxyindoleacetic acid (FHIAA), and intermediaries in the Citric Acid Cycle.

[0254] Many embodiments described herein use an adhesive (e.g., the adhesive 126 in Figure 7). One purpose of the adhesive can be to couple a base, a sensor module, and/or a sensor to a host (e.g., to skin of the host). The adhesive can be configured for adhering to skin. The adhesive can include a pad (e.g., that is located between the adhesive and the base). Additional adhesive information, including adhesive pad information, is described in U.S. Patent Application No. 14/835,603, which was filed on August 25, 2015. The entire contents of U.S. Patent Application No. 14/835,603 are incorporated by reference herein.

DISTAL BASE LOCATION

[0255] As noted above, systems can apply an on-skin sensor assembly to the skin of a host. The system can include a base that comprises an adhesive to couple a glucose sensor to the skin.

[0256] In some applicators, the base is hidden deep inside the applicator until the user moves the needle distally with the base. One challenge with this approach is that the insertion site (on the skin of the host) is not ideally prepared for sensor and/or needle insertion. For example, the distal end of the applicator may be a hoop that presses against the skin. The pressure of the applicator on the skin can cause the area of the skin within the hoop to form a convex shape. In addition, the skin within the hoop can be too easily compressed such that the skin lacks sufficient resilience and firmness. In this state, the sensor and/or needle may press the skin downward without immediately piercing the skin, which may result in improper sensor and/or needle insertion.

[0257] In several embodiments, the base is coupled to a telescoping assembly such that the base protrudes from the distal end of the system while the glucose sensor is located remotely from the base and is located within the telescoping assembly. This configuration enables the base to prepare the insertion site of the skin for sensor and/or needle insertion (e.g., by compressing the skin). Thus, these embodiments can dramatically improve the reliability of sensor and/or needle insertion while reducing pain associated with sensor and/or needle insertion.

[0258] The system can hold the base in a position that is distal relative to a glucose sensor module such that a glucose sensor is not attached to the base and such that the glucose sensor can move relative to the base. Moving the glucose sensor module distally towards the base can attach the glucose sensor to the base. This movement can occur as a result of compressing an applicator.

[0259] Figure 2 illustrates a perspective view of an applicator system 104 for applying at least portions of an on-skin sensor assembly 600 (shown in Figure 4) to skin of a host (e.g., a person). The system can include a sterile barrier having a shell 120 and a cap 122. The cap 122 can screw onto the shell 120 to shield portions of the system 104 from external contaminants.

[0260] The electronics unit 500 (e.g., a transmitter having a battery) can be detachably coupled to the sterile barrier shell 120. The rest of the applicator system 104 can be sterilized, and then the electronics unit 500 can be coupled to the sterile barrier shell 120 (such that the electronics unit 500 is not sterilized with the rest of the applicator system 104).

[0261] The user can detach the electronics unit 500 from the sterile barrier shell 120. The user can also couple the electronics unit 500 to the base 128 (as shown in Figure 6) after the

applicator system 104 places at least a portion of a sensor in a subcutaneous position (for analyte sensing).

[0262] Many different sterilization processes can be used with the embodiments described herein. The sterile barrier 120 and/or the cap 122 can block gas from passing through (e.g., can be hermetically sealed). The hermetic seal can be formed by threads 140 (shown in Figure 3). The threads 140 can be compliant such that they deform to create a seal. The threads 140 can be located between the sterile barrier shell 120 and the cap 122.

[0263] The cap 122 can be made polypropylene and the shell 120 can be made from polycarbonate (or vice versa) such that one of the cap 122 and the shell 120 is harder than the other of the cap 122 and the 120. This hardness (or flexibility) difference enables one of the components to deform to create the thread 140 seal.

[0264] In some embodiments, at least one of the shell 120 and the cap 122 includes a gas-permeable material to enable sterilization gases to enter the applicator system 104. For example, as explained in the context of Figure 60, the system can include a cover 272h.

[0265] Referring now to Figure 3, the threads 140 can be configured such that a quarter rotation, at least 15 percent of a full rotation, and/or less than 50 percent of a full rotation uncouples the cap 122 from the shell 120. Some embodiments do not include threads 140. The cap 122 can be pushed onto the shell 120 (e.g., during assembly) even in some threaded embodiments.

[0266] A cap 122 can be secured to the shell 120 by a frangible member 142 configured such that removing the cap 122 from the shell 120 brakes the frangible member 142. The frangible member 142 can be configured like the safety ring (with a frangible portion) of a plastic soda bottle. Unscrewing the cap from the plastic soda bottle breaks the safety ring from the soda bottle's cap. This approach provides evidence of tampering. In the same way, the applicator system 104 can provide tamper evidence (due to the frangible member 142 being broken by removing the cap 122 from the shell 122).

[0267] U.S. Patent Publication No. US-2013-0267811-A1; U.S. Patent Application No. 62/165,837, which was filed on May 15, 2015; and U.S. Patent Application No. 62/244,520, which was filed on October 21, 2015, include additional details regarding applicator system embodiments. The entire contents of U.S. Patent Publication No. US-2013-0267811-A1; U.S.

Patent Application No. 62/165,837; and U.S. Patent Application No. 62/244,520 are incorporated by reference herein.

[0268] Figure 3 illustrates a cross-sectional view of the system 104. A glucose sensor module 134 is configured to couple a glucose sensor 138 to the base 128 (e.g., a "housing"). The telescoping assembly 132 is located in a proximal starting position such that the glucose sensor module 134 is located proximally relative to the base 128 and remotely from the base 128. The telescoping assembly 132 is configured such that collapsing the telescoping assembly 132 connects the glucose sensor module 134 to the base 128 via one or more mechanical interlocks (e.g., snap fits, interference features).

[0269] The sterile barrier shell 120 is coupled to a telescoping assembly 132. After removing the cap 122, the system 104 is configured such that compressing the sterile barrier shell 120 distally (while a distal portion of the system 104 is pressed against the skin) can insert a sensor 138 (shown in Figure 4) into the skin of a host to place the transcutaneous, glucose analyte sensor 138. In many figures shown herein, the sterile barrier shell 120 and cap 122 are hidden to increase the clarity of other features.

[0270] Collapsing the telescoping assembly 132 also pushes at least 2.5 millimeters of the glucose sensor 138 out through a hole in the base 128 such that at least 2.5 millimeters of the glucose sensor 138 that was previously located proximally relative to a distal end of the base protrudes distally out of the base 128. Thus, in some embodiments, the base 128 can remain stationary relative to a distal portion of the telescoping assembly 132 while the collapsing motion of the telescoping assembly 132 brings the glucose sensor module 134 towards the base 128 and then couples the sensor module 134 to the base 128.

[0271] This relative motion between the sensor module 134 and the base 128 has many benefits, such as enabling the base to prepare the insertion site of the skin for sensor and/or needle insertion (e.g., by compressing the skin). The starting position of the base 128 also enables the base 128 to shield people from a needle, which can be located inside the applicator system 104. For example, if the base 128 were directly coupled to the sensor module 134 in the proximal starting position of the telescoping assembly, the needle may protrude distally from the base 128. The exposed needle could be a potential hazard. In contrast, the distal starting position of the base 128 enables the base 128 to protect people from inadvertent needle insertion.

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Needle protection is especially important for caregivers (who are not the intended recipients of the on-skin sensor assembly 600 shown in Figure 4).

[0272] Figure 4 illustrates a perspective view of the on-skin sensor assembly 600, which includes the base 128. An adhesive 126 can couple the base 128 to the skin 130 of the host. The adhesive 126 can be a foam adhesive suitable for skin adhesion. A glucose sensor module 134 is configured to couple a glucose sensor 138 to the base 128.

[0273] The applicator system 104 (shown in Figure 2) can couple the adhesive 126 to the skin 130. The system 104 can also secure (e.g., couple via mechanical interlocks such as snap fits and/or interference features) the glucose sensor module 134 to the base 128 to ensure the glucose sensor 138 is coupled to the base 128. Thus, the adhesive 126 can couple the glucose sensor 138 to the skin 130 of the host.

[0274] After the glucose sensor module 134 is coupled to the base 128, a user (or an applicator) can couple the electronics unit 500 (e.g., a transmitter) to the base 128 via mechanical interlocks such as snap fits and/or interference features. The electronics unit 500 can measure and/or analyze glucose indicators sensed by the glucose sensor 138. The electronics unit 500 can transmit information (e.g., measurements, analyte data, glucose data) to a remotely located device (e.g., 110-113 shown in Figure 1).

[0275] Figure 5 illustrates a perspective view of the electronics unit 500 coupled to the base 128 via mechanical interlocks such as snap fits and/or interference features. Adhesive 126 on a distal face of the base 128 is configured to couple the sensor assembly 600 to the skin. Figure 6 illustrates another perspective view of the electronics unit 500 coupled to the base 128.

[0276] Any of the features described in the context of Figures 1-6 can be applicable to all aspects and embodiments identified herein. For example, many embodiments can use the on-skin sensor assembly 600 shown in Figure 4 and can use the sterile barrier shell 120 shown in Figure 2. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0277] Figures 7-11 illustrate cross-sectional views of the applicator system 104 from Figure 3. The sterile barrier shell 120 and the cap 134 are hidden in Figures 7-11 to facilitate viewing the telescoping assembly 132.

[0278] The telescoping assembly 132 is part of a system for applying an on-skin sensor assembly 600 to skin of a host (shown in Figure 4). The telescoping assembly 132 can apply portions of the system to the host. Additional portions of the system can be added to the on-skin sensor assembly 600 after the applicator system 104 couples initial portions of the sensor assembly 600 to the host. For example, as shown in Figure 4, the electronics unit 500 (e.g., a transmitter) can be coupled to the on-skin sensor assembly 600 after the applicator system 104 (shown in figure 3) couples the base 128, the glucose sensor module 134, and/or the glucose sensor 138 to the skin 130 of the host.

[0279] In some embodiments, the applicator system 104 (shown in Figure 3) couples at least one, at least two, at least three, at least four, and/or all of the following items to the skin of the host: the electronics unit 500, the glucose sensor module 134, the glucose sensor 138, the base 128, and the adhesive 126. The electronics unit 500 can be located inside the applicator system 104 such that the applicator system 104 is configured to couple the electronics unit 500 to the skin of the host.

[0280] Figure 7 illustrates a telescoping assembly 132 having a first portion 150 (e.g., a "pusher") configured to move distally relative to a second portion 152 (e.g., a "needle guard") from a proximal starting position to a distal position along a path 154. Figure 7 illustrates the telescoping assembly 132 in the proximal starting position. Figure 8 illustrates the telescoping assembly 132 moving between the proximal starting position and the distal position. Figure 11 illustrates the telescoping assembly 132 in the distal position. The path 154 (shown in Figure 7) represents the travel between the proximal starting position and the distal position.

[0281] A first set of items can be immobile relative to the first portion 150, and a second set of items can be immobile relative to the second portion 152 while the first set of items move relative to the second set of items.

[0282] Referring now to Figure 7, the glucose sensor 138 and the sensor module 134 are coupled to the first portion 150 (e.g., such that they are immobile relative to the first portion 150 during a proximal portion of the path 154). The base 128 is coupled to the second portion 152 such that the base 128 protrudes from a distal end of the system (e.g., the base protrudes from a

distal end of the telescoping assembly 132). The base 128 comprises adhesive 126 configured to eventually couple the glucose sensor 138 to the skin (e.g., after at least a portion of the glucose sensor 138 is rigidly coupled to the base 128).

[0283] In Figure 7, the glucose sensor 138 and the sensor module 134 are located within the second portion 152 while the base 128 protrudes from the distal end of the system (e.g., from the distal end of the telescoping assembly 132) such that the system is configured to couple the glucose sensor 138 to the base 128 via moving the first portion 150 distally relative to the second portion 152. The progression shown in Figures 7-11 illustrates moving the first portion 150 distally relative to the second portion 152.

[0284] The sensor module 138 is coupled to a distal portion of the first portion 150 such that moving the first portion 150 to the distal position (as described above) couples the sensor module 134 to the base 128. The glucose sensor 138 is coupled to the sensor module 134 (e.g., immobile relative to the sensor module 134) while the first portion 150 is located in the proximal starting position. The glucose sensor 138 can include a distally protruding portion and a proximal portion. The proximal portion can be rigidly coupled to the sensor module 134 such that the proximal portion cannot move relative to the sensor module 134 even though the distally protruding portion may bend relative to the sensor module 134.

[0285] A needle 156 (e.g., a "C-shaped" needle) is coupled to the first portion 150 such that the glucose sensor 138 and the needle 156 move distally relative to the base 128 and relative to the second portion 152. The system can further comprise a needle release mechanism 158 configured to retract the needle 156 proximally.

[0286] The needle 156 can have many different forms. Many different types of needles 156 can be used with the embodiments described herein. Figures 51-55 illustrate various needle embodiments that can be used with any of the embodiments described herein.

[0287] The needle 156 can guide the sensor 138 into the skin of the host. A distal portion of the sensor 138 can be located in a channel of the needle 156 (as shown in Figure 42). Sometimes, a distal end of the sensor 138 sticks out of the needle 156 and gets caught on tissue of the host as the sensor 138 and needle 156 are inserted into the host. As a result, the sensor 138 may buckle and fail to be inserted deeply enough into the subcutaneous tissue. In other words, in some embodiments, the sensor wire must be placed within the channel of the C-shaped

needle 156 to be guided into the tissue and must be retained in the channel 330 during deployment.

[0288] The risk of the sensor 138 sticking out of the channel 330 (and thereby failing to be property inserted into the host) can be greatly diminished by the embodiment illustrated in Figure 51. In this embodiment, adhesive 376 bonds a distal portion of the glucose sensor 138 into the channel 330 of the needle 156. Retracting the needle 156 can break the bond of the adhesive 376 to enable a distal portion of the sensor 138 to stay in a subcutaneous location while the needle 156 is retracted (and even after the needle 156 is retracted).

[0289] The risk of the sensor 138 sticking out of the channel 330 (and thereby failing to be property inserted into the host) can be greatly diminished by the embodiment illustrated in Figures 52 and 53. In this embodiment, the needle 156a comprises two sides, which can be separated by slots 378. The sensor 138 can have a width that is larger than the width of the slots 378 such that the sensor 138 cannot come out of the channel 330a until the two sides of the needle 156a are moved apart (to widen the slots 378).

[0290] The embodiment illustrated in Figure 54 can be used with any of the other embodiments described herein. The needle 156b includes a ramp 380 at the distal end of the channel 330b. The distal end of the needle 156b can include a conical tip 382. The ramp 380 can be configured to push the sensor 138 out of the channel 330b of the needle 156b as the needle 156b is retracted into the telescoping assembly 132 (shown in Figure 7).

[0291] Figure 55 illustrates cross sectional views of different needles 156c, 156d, 156e, 156f, which can be used as needle 156 in Figure 7 or in any other embodiment described herein. Needle 156c includes an enclosed channel 330c. Needles 156d, 156e, 156f are C-needles, although many other C-needle shapes can be used in several embodiments. The ends of the needle 156d can be angled relative to each other. In some embodiments, the ends of the needle can be angled away from each other, in an opposite fashion as shown by 156d. In some embodiments, the ends of the needle can have flared edges, in which the flared edges are rounded to prevent the sensor from contacting sharp edges. The ends of the needle 156e can be parallel and/or flat relative to each other. The outside portion of the channel 330f can be formed by walls that are straight and/or parallel to each other (rather than by curved walls as is the case for other needles 156d, 156e). Some needles 156d can be manufactured via laser cutting, some

needles 156e can be manufactured via wire electrical discharge machining ("EDM"), and some needles 156f can be manufactured via stamping.

[0292] As shown in Figure 7, a needle hub 162 is coupled to the needle 156. The needle hub includes release features 160 that protrude outward. In some embodiments, the release features can comprise one, two, or more flexible arms. Outward ends 164 of the release features 160 catch on inwardly facing overhangs 166 (e.g., undercuts, detents) of the first portion 150 such that moving the first portion 150 distally relative to the second portion 152 causes the needle retraction mechanism 158 to move distally until a release point.

[0293] At the release point, proximal protrusions 170 of the second portion 152 engage the release features 160 (shown in Figure 9), which forces the release features 160 to bend inward until the release features 160 no longer catch on the overhangs 166 of the first portion 150 (shown in Figure 10). Once the release features 160 no longer catch on the overhangs 166 of the first portion 150, the spring 234 of the needle retraction mechanism 158 pushes the needle 156 and the needle hub 162 proximally relative to the first portion 150 and relative to the second portion 152 until the needle no longer protrudes distally from the base 128 and is completely hidden inside the telescoping assembly 132 (shown in Figure 11).

[0294] The needle 156 can be removed from the embodiment illustrated in Figure 7 to make a needle-free embodiment. Thus, a needle 156 is not used in some embodiments. For example, a distal end of the glucose sensor 138 can be formed in a conical shape to enable inserting the glucose sensor 138 into the skin without using a needle 156. Unless otherwise noted, the embodiments described herein can be formed with or without a needle 156.

[0295] In several embodiments, a needle can help guide the glucose sensor 138 (e.g., at least a distal portion of the glucose sensor) into the skin. In some embodiments, a needle is not part of the system and is not used to help guide the glucose sensor 138 into the skin. In needle embodiments and needle-free embodiments, skin piercing is an important consideration. Failing to properly pierce the skin can lead to improper placement of the glucose sensor 138.

[0296] Tensioning the skin prior to piercing the skin with the glucose sensor 138 and/or the needle 156 can dramatically improve the consistency of achieving proper placement of the glucose sensor 138. Tensioning the skin can be accomplished by compressing the skin with a distally protruding shape (e.g., a convex shape) prior to piercing the skin and at the moment of piercing the skin with the glucose sensor 138 and/or the needle 156.

[0297] Figure 12A illustrates a portion of the cross section shown in Figure 7. The base 128 includes an optional distally facing protrusion 174 located distally relative to the second portion 152 (and relative to the rest of the telescoping assembly 132). The distal protrusion 174 is convex and is shaped as a dome. In some embodiments, the distal protrusion 174 has block shapes, star shapes, and cylindrical shapes. Several base 128 embodiments do not include the protrusion 174.

[0298] The distal protrusion 174 can be located farther distally than any other portion of the base 128. The distal protrusion 174 can extend through a hole 176 in the adhesive 126 (as also shown in Figure 5). A distal portion of the convex protrusion 174 can be located distally relative to the adhesive 126 while a proximal portion of the convex protrusion 174 is located proximally relative to the adhesive 126.

[0299] The distal protrusion 174 has a hole 180 through which the needle 156 and/or the glucose sensor 138 can pass. The distal protrusion 174 can compress the skin such that the distal protrusion 174 is configured to reduce a resistance of the skin to piercing.

[0300] Figure 12B illustrates a cross sectional view of a base 128b that is identical to the base 128 illustrated in Figures 7 and 12B except for the following features: The base 128b does not include a protrusion 174. The base 128b includes a funnel 186 (e.g., a radius) on the distal side of the hole 180b.

[0301] Like the embodiment shown in Figure 12A, the sensor 138 (e.g., an analyte sensor) and/or the needle 156 (shown in Figure 12A) can pass through the hole 180b (shown in Figure 12B). The funnels 182, 186 can be mirror images of each other or can be different shapes. The base 128b can be used with any of the embodiments described herein.

[0302] Figure 13 illustrates a perspective view of a portion of the adhesive 126. The needle 156 can have many different shapes and cross sections. In some embodiments, the needle 156 includes a slot 184 (e.g., the channel 330 shown in Figures 42 and 43) into which at least a portion of the glucose sensor 138 can be placed.

[0303] The needle 156 having a slot 184 passes through the hole 180 of the distal protrusion and through the hole 176 of the adhesive 126. A portion of the glucose sensor 138 is located in the slot 184 such that the needle 156 is configured to move distally relative to the base 128 (shown in Figure 12A) without dislodging the portion of the glucose sensor 138 from the slot 184. The distal protrusion 174 is convex such that the distal protrusion 174 is configured to

tension the skin while the first portion 150 moves distally relative to the second portion 152 of the telescoping assembly 132 (shown in Figure 7) to prepare the skin for piercing.

[0304] As mentioned above, the adhesive 126 comprises a hole 176 through which at least a portion of the distal protrusion 174 of the base 128 can pass. The distal protrusion 174 is located within the hole 176 of the adhesive 126 such that the distal protrusion 174 can tension at least a portion of the skin within the second hole (e.g., located under the hole 176). The hole 176 can be circular or any other suitable shape. The hole 176 can be sized such that at least a majority of the distal protrusion 174 extends through the hole 176. A perimeter of the hole 176 can be located outside of the distal protrusion 174 such that the perimeter of the hole 176 is located radially outward relative to a perimeter of the protrusion 174 where the protrusion 174 connects with the rest of the base 128.

[0305] In some embodiments, the hole 176 of the adhesive 126 is large enough that the adhesive 126 does not cover any of the distal protrusion 174. In some embodiments, the adhesive 126 covers at least a portion of or even a majority of the distal protrusion 174. Thus, the adhesive 126 does not have to be planar and can bulge distally in an area over the distal protrusion 174.

[0306] In several embodiments, the adhesive 126 has a non-uniform thickness such that the thickness of the adhesive 126 is greater in an area surrounding a needle exit area than in other regions that are farther radially outward from the needle exit area. Thus, the distal protrusion 174 can be part of the adhesive 126 rather than part of the base 128. However, in several embodiments, the base 128 comprises the adhesive 126, and the distal protrusion 174 can be formed by the plastic of the base 128 or by the foam adhesive 126 of the base 128.

[0307] The needle 156 includes a distal end 198 and a heel 194. The heel 194 is the proximal end of the angled portion of the needle's tip. The purpose of the angled portion is to form a sharp end to facilitate penetrating tissue. The sensor 138 has a distal end 208.

[0308] During insertion of the needle 156 and the sensor 138 into the tissue; as the needle 156 and the sensor 138 first protrude distally from the system; and/or while the needle 156 and the sensor 138 are located within the telescoping assembly, the end 208 of the sensor 138 can be located at least 0.1 millimeter proximally from the heel 194, less than 1 millimeter proximally from the heel 194, less than 3 millimeters proximally from the heel 194, and/or within plus or minus 0.5 millimeters of the heel 194; and/or the end 208 of the sensor 138 can be located at

least 0.3 millimeters proximally from the distal end 198 of the needle 156 and/or less than 2 millimeters proximally from the distal end 198.

[0309] Referring now to Figure 12A, the distal protrusion 174 can protrude at least 0.5 millimeters and less than 5 millimeters from the distal surface of the adhesive 126. In embodiments where the adhesive 126 has a non-planar distal surface, the distal protrusion 174 can protrude at least 0.5 millimeters and less than 5 millimeters from the average distal location of the adhesive 126.

[0310] As described above, in some embodiments the base is coupled to a telescoping assembly such that the base protrudes from the distal end of the system while the glucose sensor is located remotely from the base and is located within the telescoping assembly. In other embodiments, however, the base is coupled to a telescoping assembly such that the base is located completely inside the telescoping assembly and the base moves distally with the sensor as the first portion is moved distally relative to the second portion of the telescoping assembly.

[0311] For example, Figure 59 illustrates a base 128 coupled to the sensor module 134 and to the sensor 138 while the first portion 150 of the telescoping assembly 132f is located in the proximal starting position. The base 128 moves distally as the first portion 150 is moved distally relative to the second portion 152. The base 128 can be coupled to a distal end portion of the first portion 150 while the first portion 150 is located in the proximal starting position. All of the features and embodiments described herein can be configured and used with the base 128 positioning described in the context of Figure 59.

[0312] All of the embodiments described herein can be used with the base coupled to a telescoping assembly such that the base is located completely inside the telescoping assembly and the base moves distally with the sensor as the first portion is moved distally relative to the second portion of the telescoping assembly. All of the embodiments described herein can be used with the base coupled to a telescoping assembly such that the base protrudes from the distal end of the system while the glucose sensor is located remotely from the base and is located within the telescoping assembly.

SENSOR MODULE DOCKING AND BASE DETACHMENT

[0313] As explained above, maintaining the base against the skin during insertion of the sensor and/or needle enables substantial medical benefits. Maintaining the base against the skin, however, can necessitate moving the sensor relative to the base during the insertion process.

Once inserted, the sensor needs to be coupled to the base to prevent the sensor from inadvertently dislodging from the base. Thus, there is a need for a system that enables the sensor to move relative to the base and also enables locking the sensor to the base (without being overly burdensome on users).

[0314] Maintaining the base against the skin during the distal movement of the sensor and/or needle is enabled in many embodiments by unique coupling systems that secure the sensor (and the sensor module) to a first portion of a telescoping assembly and secure the base to a second portion of the telescoping assembly. Moving the first portion towards the second portion of the telescoping assembly can align the sensor with the base while temporarily holding the sensor. Then, the system can couple the sensor to the base. Finally, the system can detach the base and sensor from the telescoping assembly (which can be disposable or reusable with a different sensor).

[0315] As illustrated in Figure 4, the sensor module 134 and the glucose sensor 138 are not initially coupled to the base 128. Coupling the sensor module 134 and the glucose sensor 138 to the base 128 via compressing the telescoping assembly 132 and prior to detaching the base 128 from the telescoping assembly 132 can be a substantial challenge, yet is enabled by many of the embodiments described herein.

[0316] As illustrated in Figures 7 and 14, the sensor module 134 (and the glucose sensor 138) can be located remotely from the base 128 even though they are indirectly coupled via the telescoping assembly 132. In other words, the sensor module 134 (and the glucose sensor 138) can be coupled to the first portion 150 of the telescoping assembly 132 while the base 128 is coupled to the second portion 152 of the telescoping assembly 132. In this state, the sensor module 134 and the glucose sensor 138 can move relative to the base 128 (e.g., as the sensor module 134 and the glucose sensor 138 move from the proximal starting position to the distal position along the path to "dock" the sensor module 134 and the glucose sensor 138 to the base 128).

[0317] After the sensor module 134 and the glucose sensor 138 are "docked" with the base 128, the system can detach the base 128 from the telescoping assembly 132 to enable the sensor module 134, the glucose sensor 138, and the base 128 to be coupled to the skin by the adhesive 126 while the telescoping assembly 132 and other portions of the system are discarded.

[0318] As shown in Figure 7, the sensor module 134 is coupled to the first portion 150 and is located at least 5 millimeters from the base 128 while the first portion 150 is in the proximal starting position. The system is configured such that moving the first portion 150 to the distal position couples the sensor module 134 to the base 128 (as shown in Figure 11). The glucose sensor 138 is coupled to the sensor module 134 while the first portion 150 is located in the proximal starting position. The glucose sensor 138 is located within the second portion 152 while the base 128 protrudes from the distal end of the system.

[0319] Arrow 188 illustrates the proximal direction in Figure 7. Arrow 190 illustrates the distal direction in Figure 7. Line 172 illustrates a horizontal orientation. As used herein, horizontal means within plus or minus 20 degrees of perpendicular to the central axis 196.

[0320] Figure 15 illustrates a perspective view of a cross section of portions of the system shown in Figure 7. The cross section cuts through the hole 180 of the base 128. Visible portions include the sensor module 134, the sensor 138, a seal 192, the needle 156, the base 128, and the adhesive 126. The sensor module 134 is in the proximal starting position. The seal 192 is configured to block fluid (e.g., bodily fluid) from entering the glucose sensor module 134.

[0321] The glucose sensor 138 is mechanically coupled to the sensor module 134. The glucose sensor 138 runs into an interior portion of the sensor module 134 and is electrically coupled to interconnects in the interior portion of the sensor module 134. The interconnects are hidden in Figure 15 to facilitate seeing the proximal portion of the glucose sensor 138 inside the interior portion of the sensor module 134. Many other portions of the system are also hidden in Figure 15 to enable clear viewing of the visible portions.

[0322] In many embodiments, the sensor module 134 moves from the position shown in Figure 15 until the sensor module 134 snaps onto the base 128 via snap fits that are described in more detail below. Figure 11 illustrates the sensor module 134 snapped to the base 128. This movement from the proximal starting position to the "docked" position can be accomplished by moving along the path 154 (shown in Figure 7 and illustrated by the progression in Figures 7-11). (The arrow representing the path 154 is not necessarily drawn to scale.)

[0323] Referring now to Figures 7 and 15, during a first portion of the path 154, the sensor module 134 is immobile relative to the first portion 150, and the base 128 is immobile relative to the second portion 152 of the telescoping assembly 132. During a second portion of the path 154, the system is configured to move the first portion 150 distally relative to the second

portion 152; to move the sensor module 134 towards the base 128; to move at least a portion of the sensor 138 through a hole 180 in the base 128; to couple the sensor module 134 to the base 128; and to enable the coupled sensor module 134 and the base 128 to detach from the telescoping assembly 132.

[0324] Figure 7 illustrates a vertical central axis 196 oriented from a proximal end to the distal end of the system. (Part of the central axis 196 is hidden in Figure 7 to avoid obscuring the arrow that represents the path 154 and to avoid obscuring the needle 156.)

[0325] Figure 15 illustrates a flex arm 202 of the sensor module 134. The flex arm 202 is oriented horizontally and is configured to secure the sensor module 134 to a protrusion of the base 128. In some embodiments, the flex arm 202 is an alignment arm to prevent and/or impede rotation of the sensor module 134 relative to the base 128.

[0326] Figure 16 illustrates a perspective view of a cross section in which the sensor module 134 is coupled to the base 128 via flex arms 202. Interconnects 204 protrude proximally to connect the sensor module 134 to the electronics unit 500 (e.g., a transmitter).

[0327] Referring now to Figures 15 and 16, the flex arms 202 extend from an outer perimeter of the sensor module 134. The base 128 comprises protrusions 206 that extend proximally from a planar, horizontal portion of the base 128.

[0328] Referring now to Figure 16, each of the proximal protrusions 206 of the base 128 are coupled to a flex arm 202 of the sensor module 134. Thus, the coupling of the proximal protrusions 206 to the flex arms 202 couples the sensor module 134 to the base 128.

[0329] Each proximal protrusion 206 can include a locking protrusion 212 that extends at an angle of at least 45 degrees from a central axis of each proximal protrusion 206. In some embodiments, the locking protrusions 212 extend horizontally (e.g., as shown in Figure 15). Each horizontal locking protrusion 212 is coupled to an end portion 210 of a flexible arm 202.

[0330] The end portion 210 of each flexible arm 202 can extend at an angle greater than 45 degrees and less than 135 degrees relative to a central axis of the majority of the flexible arm 202. The end portion 210 of each flexible arm 202 can include a horizontal locking protrusion (e.g., as shown in Figure 15).

[0331] In Figures 15 and 16, a first horizontal locking protrusion is coupled to an end portion 210 of the first flexible arm 202. A second horizontal locking protrusion 212 is coupled to the first proximal protrusion 206 of the base 128. In Figure 16, the first horizontal locking

protrusion is located distally under the second horizontal locking protrusion 212 to secure the sensor module 134 to the base 128. The system is configured such that moving the first portion 150 of the telescoping assembly 132 to the distal position (shown in Figure 11) causes the first flex arm 202 to bend to enable the first horizontal locking protrusion of the flex arm 202 to move distally relative to the second horizontal locking protrusion 212. Thus, the flex arm 202 is secured between the locking protrusion 212 and the distal face of the base 128.

[0332] At least a portion of the flex arm 202 (e.g., the end portion 210) is located distally under the horizontal locking protrusion 212 of the base 128 to secure the sensor module 134 to the base 128. The system is configured such that moving the first portion 150 of the telescoping assembly 132 to the distal position causes the flex arm 202 (e.g., the end portion 210) to bend away (e.g., outward) from the rest of the sensor module 134 to enable the horizontal locking protrusion of the flex arm 202 to go around the locking protrusion 212 of the proximal protrusion 206. Thus, at least a portion of the flex arm 202 can move distally relative to the horizontal locking protrusion 212 of the proximal protrusion 206 of the base 128.

[0333] The sensor module 134 can have multiple flex arms 202 and the base can have multiple proximal protrusions 206 configured to couple the sensor module 134 to the base 128. In some embodiments, a first flex arm 202 is located on an opposite side of the sensor module 134 relative to a second flex arm 202 (e.g., as shown in Figures 15 and 16).

[0334] In some embodiments, the base 128 comprises flex arms (e.g., like the flex arms 202 shown in Figures 15 and 16) and the sensor module 134 comprises protrusions that couple to the flex arms of the base 128. The protrusions of the sensor module 134 can be like the protrusions 206 shown in Figures 15 and 16 except that, in several embodiments, the protrusions extend distally towards the flex arms of the base 128. Thus, the base 128 can be coupled to the sensor module 134 with flex arms and mating protrusions regardless of whether the base 128 or the sensor module 134 includes the flex arms.

[0335] In several embodiments, a sensor module is coupled to the glucose sensor. The system comprises a vertical central axis oriented from a proximal end to the distal end of the system. The base comprises a first flex arm that is oriented horizontally and is coupled to the sensor module. The sensor module comprises a first distal protrusion coupled to the first flex arm to couple the sensor module to the base. A first horizontal locking protrusion is coupled to an end portion of the first flexible arm. A second horizontal locking protrusion is coupled to the

first distal protrusion of the sensor module. The second horizontal locking protrusion is located distally under the first horizontal locking protrusion to secure the sensor module to the base. The system is configured such that moving the first portion of the telescoping assembly to the distal position causes the first flex arm to bend to enable the second horizontal locking protrusion to move distally relative to the first horizontal locking protrusion. The sensor module comprises a second distal protrusion coupled to a second flex arm of the base. The first distal protrusion is located on an opposite side of the sensor module relative to the second distal protrusion.

[0336] Docking the sensor module 134 to the base 128 can include securing the sensor module 134 to the first portion 150 of the telescoping assembly 132 while the first portion 150 moves the sensor module 134 towards the base 128. This securing of the sensor module 134 to the first portion 150 of the telescoping assembly 132 needs to be reliable, but temporary so the sensor module 134 can detach from the first portion 150 at an appropriate stage. The structure that secures the sensor module 134 to the first portion 150 of the telescoping assembly 132 generally needs to avoid getting in the way of the docking process.

[0337] Figure 17 illustrates a cross-sectional view of the first portion 150 of the telescoping assembly 132. Figure 17 shows the glucose sensor module 134 and the needle 156. Some embodiments do not include the needle 156. Many items are hidden in Figure 17 to provide a clear view of the flex arms 214, 216 of the first portion 150.

[0338] The first portion 150 comprises a first flex arm 214 and a second flex arm 216 that protrude distally and latch onto the sensor module 134 to releasably secure the sensor module 134 to the first portion 150 while the first portion 150 is in the proximal starting position (shown in Figure 7). The flex arms 214, 216 can couple to an outer perimeter of the sensor module 134 such that distal ends of the flex arms 214, 216 wrap around a distal face of the sensor module 134. In some embodiments, the distal ends of the flex arms 214, 216 are located distally of the sensor module 134 while the first portion 150 is in the proximal starting position.

[0339] The base 128 is hidden in Figure 17, but in the state illustrated in Figure 17, the sensor module 134 is located remotely from the base 128 to provide a distance of at least 3 millimeters from the sensor module 134 to the base 128 while the first portion 150 is in the proximal starting position. This distance can be important to enable the base to rest on the skin as the needle 156 and/or the glucose sensor 138 pierce the skin and advance into the skin during the transcutaneous insertion.

[0340] Referring now to Figures 7 and 17, the sensor module 134 is located within the second portion 152 while the base 128 protrudes from the distal end of the system such that the system is configured to couple the sensor module 134 to the base 128 via moving the first portion 150 distally relative to the second portion 152. The sensor module 134 is located within the second portion 152 while the base 128 protrudes from the distal end of the system even though the sensor module 134 is moveable relative to the second portion 152 of the telescoping assembly 132. Thus, the first portion 150 moves the sensor module 134 through an interior region of the second portion 152 of the telescoping assembly 132 without moving the base 128 through the interior region of the second portion 152.

[0341] The system comprises a vertical central axis 196 oriented from a proximal end to the distal end of the system. The first flex arm 214 and the second flex arm 216 of the first portion 150 secure the sensor module 134 to the first portion 150 such that the sensor module 134 is releasably coupled to the first portion 150 with a first vertical holding strength (measured along the vertical central axis 196).

[0342] As shown in Figures 15 and 16, the sensor module 134 is coupled to the base 128 via at least one flex arm 202 such that the sensor module 134 is coupled to the base 128 with a second vertical holding strength. The flex arms 202 can extend from an outer perimeter of the sensor module 134. The flex arms 202 can be part of the base 128.

[0343] Referring now to Figure 17, in some embodiments, the second vertical holding strength is greater than the first vertical holding strength such that continuing to push the first portion 150 distally once the sensor module 134 is coupled to the base 128 overcomes the first and second flex arms 214, 216 of the first portion 150 to detach the sensor module 134 from the first portion 150.

[0344] In some embodiments, the second vertical holding strength is at least 50 percent greater than the first vertical holding strength. In several embodiments, the second vertical holding strength is at least 100 percent greater than the first vertical holding strength. In some embodiments, the second vertical holding strength is less than 400 percent greater than the first vertical holding strength.

[0345] Figure 6 illustrates the on-skin sensor assembly 600 in a state where it is attached to a host. The on-skin sensor assembly 600 can include the glucose sensor 138 and/or the sensor module 134 (shown in Figure 7). In some embodiments, the on-skin sensor assembly 600

includes the needle 156. In several embodiments, however, the on-skin sensor assembly 600 does not include the needle 156.

[0346] As explained above, maintaining the base against the skin during insertion of the sensor and/or needle enables substantial medical benefits. Maintaining the base against the skin, however, can complicate detaching the base from the applicator. For example, in some prior-art systems, the base detaches after the base moves downward distally with a needle. This relatively long travel can enable several base detachment mechanisms. In contrast, when the base is maintained in a stationary position as the needle moves towards the base, releasing the base can be problematic.

[0347] Many embodiments described herein enable maintaining the base 128 against the skin during insertion of the sensor 138 and/or the needle 156. As mentioned above in the context of Figures 7-11, after the sensor module 134 is coupled to the base 128, the sensor module 134 and the base 128 need to detach from the telescoping assembly 132 to secure the glucose sensor 138 to the host and to enable the telescoping assembly to be thrown away, recycled, or reused.

[0348] As shown in Figures 7-11, several embodiments hold the base 128 in a stationary position relative to the second portion 152 of the telescoping assembly 132 as the sensor module 134 moves towards the base 128. Referring now to Figure 18, once the sensor module 134 is attached to the base 128, the system can release the base 128 by bending flex arms 220 that couple the base 128 to the second portion 152. Figure 18 shows the system in a state prior to the sensor module 134 docking with the base 128 to illustrate distal protrusions 222 of the first portion 150 aligned with the flex arms 220 such that the distal protrusions 222 are configured to bend the flex arms 220 (via the distal protrusions 222 contacting the flex arms 220).

[0349] The distal protrusions 222 bend the flex arms 220 to detach the base 128 from the telescoping assembly 132 (shown in Figure 7) after the sensor module 134 is coupled to the base 128 (as shown in Figures 11 and 16). The flex arms 220 can include a ramp 224. A distal end of the distal protrusions 222 can contact the ramp 224 and then can continue moving distally to bend the flex arm 220 as shown by arrow 228 in Figure 18. This bending can uncouple the flex arm 220 from a locking feature 230 of the base 128. This unlocking is accomplished by the first portion 150 moving distally relative to the second portion 152, which causes the distal protrusions 222 to move as shown by arrow 226.

[0350] An advantage of the system shown in Figure 18 is that the unlocking movement (of the arm 220 bending as shown by arrow 228) is perpendicular (within plus or minus 20 degrees) to the input force (e.g., as represented by arrow 226). Thus, the system is designed such that the maximum holding capability (e.g., of the locking feature 230) can be many times greater than the force necessary to unlock the arm 220 from the base 128. As a result, the system can be extremely reliable and insensitive to manufacturing variability and normal use variations.

[0351] In contrast, if the holding force and the unlocking force were oriented along the same axis (e.g., within plus or minus 20 degrees), the holding force would typically be equal to or less than the unlocking force. However, the unique structure shown in Figure 18 allows the holding force to be at least two times larger (and in some cases at least four times larger) than the unlocking force. As a result, the system can prevent inadvertent unlocking of the base 128 while having an unlocking force that is low enough to be easily provided by a user or by another part of the system (e.g., a motor).

[0352] Another advantage of this system is that it controls the locking and unlocking order of operation. In other words, the structure precludes premature locking and unlocking. In a medical context, this control is extremely valuable because reliability is so critical. For example, in several embodiments, the process follows this order: The sensor module 134 couples to the base 128. Then, the first portion 150 releases the sensor module 134. Then, the second portion 152 releases the base 128. In several embodiments, the vertical locations of various locking and unlocking structures are optimized to ensure this order is the only order that is possible as the first portion 150 moves from the proximal starting position to the distal position along the path described previously. (Some embodiments use different locking and unlocking orders of operation.)

[0353] Figure 7 illustrates the base 128 protruding from the distal end of the system while the first portion 150 of the telescoping assembly 132 is located in the proximal starting position. The sensor module 134 and at least a majority of the glucose sensor 138 are located remotely relative to the base 128. The system is configured to couple the sensor module 134 and the glucose sensor 138 to the base 128 via moving the first portion 150 distally relative to the second portion 152.

[0354] Referring now to Figures 18 and 19, the base 128 comprises a first radial protrusion 230 (e.g., a locking feature) releasably coupled with a first vertical holding strength to

a second radial protrusion 232 (e.g., a locking feature) of the second portion 152 of the telescoping assembly 132 (shown in Figure 7). The first radial protrusion 230 protrudes inward and the second radial protrusion protrudes outward 232. The system is configured such that moving the first portion 150 to the distal position moves the second radial protrusion 232 relative to the first radial protrusion 230 to detach the base 128 from the telescoping assembly 132.

[0355] The first portion 150 of the telescoping assembly 132 comprises a first arm 222 that protrudes distally. The second portion 152 of the telescoping assembly 132 comprises a second flex arm 220 that protrudes distally. The first arm 222 and the second flex arm 220 can be oriented within 25 degrees of each other (as measured between their central axes). The system is configured such that moving the first portion 150 from the proximal starting position to the distal position along the path 154 (shown in Figure 7) causes the first arm 222 to deflect the second flex arm 220, and thereby detach the second flex arm 220 from the base 128 to enable the base 128 to decouple from the telescoping assembly 132 (shown in Figure 7). Thus, the flex arm 220 is configured to releasably couple the second portion 152 to the base 128.

[0356] When the first portion 150 is in the proximal starting position, the first arm 222 of the first portion 150 is at least partially vertically aligned with the second flex arm 220 of the second portion 152 to enable the first arm 222 to deflect the second flex arm 220 as the first portion is moved to the distal position.

[0357] The first arm 222 and the second arm 220 can be oriented distally such that at least a portion of the first arm 222 is located proximally over a protrusion (e.g., the ramp 224) of the second arm 220. This protrusion can be configured to enable a collision between the first arm 222 and the protrusion to cause the second arm 220 to deflect (to detach the base 128 from the second portion 152).

[0358] In the embodiment illustrated in Figure 18, when the first portion 150 is in the proximal starting position, at least a section of the first arm 222 is located directly over at least a portion of the second flex arm 220 to enable the first arm 222 to deflect the second flex arm 220 as the first portion 150 is moved to the distal position described above. The second flex arm 220 comprises a first horizontal protrusion (e.g., the locking feature 232). The base 128 comprises a second horizontal protrusion (e.g., the locking feature 230) latched with the first horizontal protrusion to couple the base 128 to the second portion 152 of the telescoping assembly 132. The first arm 222 of the first portion 150 deflects the second flex arm 220 of the second portion

152 to unlatch the base 128 from the second portion 152, which unlatches the base 128 from the telescoping assembly 132.

[0359] Referring now to Figure 7, the system is configured to couple the glucose sensor 138 to the base 128 at a first position. The system is configured to detach the base 128 from the telescoping assembly 132 at a second position that is distal relative to the first position.

[0360] A third flex arm (e.g., flex arm 202 in Figure 15) couples the glucose sensor 138 to the base 128 at a first position. The second flex arm (e.g., flex arm 220 in Figure 18) detaches from the base at a second position. The second position is distal relative to the first position such that the system is configured to secure the base 128 to the telescoping assembly 132 until after the glucose sensor 138 is secured to the base 128.

SPRING COMPRESSION

[0361] Needles used in glucose sensor insertion applicators can be hazardous. For example, inadvertent needle-sticks can transfer diseases. Using a spring to retract the needle can reduce the risk of needle injuries.

[0362] Referring now to Figure 7, a spring 234 (e.g., a coil spring) can be used to retract the needle hub 162 that supports the c-shaped needle 156. The needle hub 162 can be released at the bottom of insertion depth (to enable the needle 156 to retract). For example, when the needle 156 reaches a maximum distal position, a latch 236 can release to enable the spring 234 to push the needle 156 proximally into a protective housing (e.g., into the first portion 150, which can be the protective housing).

[0363] Many applicators use pre-compressed springs. Many applicators use substantially uncompressed springs that are compressed by a user as the user compresses the applicator. One disadvantage of a pre-compressed spring is that the spring force can cause the components to creep (e.g., change shape over time), which can compromise the reliability of the design. One disadvantage of an uncompressed spring is that the first and second portions of the telescoping assembly can be free to move slightly relative to each other (when the assembly is in the proximal starting position). This "chatter" of the first and second portions can make the assembly seem weak and flimsy.

[0364] Many of the components described herein can be molded from plastic (although springs are often metal). Preventing creep in plastic components can help ensure that an applicator functions the same when it is manufactured and after a long period of time. One way

to reduce the creep risk is to not place the parts under a load (e.g., in storage) that is large enough to cause plastic deformation during a storage time.

[0365] Generating the retraction energy by storing energy in a spring during deployment limits the duration of load on the system. For example, the retraction force of the spring can be at least partially generated by collapsing the telescoping assembly (rather storing the system with a large retraction force of a fully pre-compressed spring).

[0366] Transcutaneous and implantable sensors are affected by the in vivo properties and physiological responses in surrounding tissues. For example, a reduction in sensor accuracy following implantation of the sensor is one common phenomenon commonly observed. This phenomenon is sometimes referred to as a "dip and recover" process. Dip and recover is believed to be triggered by trauma from insertion of the implantable sensor, and possibly from irritation of the nerve bundle near the implantation area, resulting in the nerve bundle reducing blood flow to the implantation area.

[0367] Alternatively, dip and recover may be related to damage to nearby blood vessels, resulting in a vasospastic event. Any local cessation of blood flow in the implantation area for a period of time leads to a reduced amount of glucose in the area of the sensor. During this time, the sensor has a reduced sensitivity and is unable to accurately track glucose. Thus, dip and recover manifests as a suppressed glucose signal. The suppressed signal from dip and recover often appears within the first day after implantation of the signal, most commonly within the first 12 hours after implantation. Dip and recover normally resolves within 6-8 hours.

[0368] Identification of dip and recover can provide information to a patient, physician, or other user that the sensor is only temporarily affected by a short-term physiological response, and that there is no need to remove the implant as normal function will likely return within hours.

[0369] Minimizing the time the needle is in the body limits the opportunity for tissue trauma that can lead to phenomena such as dip and recover. Quick needle retraction helps to limit the time the needle is in the body. A large spring retraction force can quickly retract the needle.

[0370] The embodiment illustrated in Figure 7 solves the "chatter" problem, avoids substantial creep, and enables quick needle retraction. The embodiment places the spring 234 in a slight preload between the first portion 150 and the second portion 152 of the telescoping

assembly 132. In other words, when the first portion 150 is in the proximal starting position, the spring 234 is in a slightly compressed state due to the relaxed length of the spring 234 being longer than the length of the chamber in which the spring 234 resides inside the telescoping assembly 132.

[0371] In some embodiments, the relaxed length of the spring 234 is at least 4 percent longer than the length of the chamber. In several embodiments, the relaxed length of the spring 234 is at least 9 percent longer than the length of the chamber. In some embodiments, the relaxed length of the spring 234 is less than 18 percent longer than the length of the chamber. In several embodiments, the relaxed length of the spring 234 is less than 30 percent longer than the length of the chamber.

[0372] The spring 234 is compressed farther when the first portion 150 is moved distally relative to the second portion 152. In some embodiments, this slight preload has a much shorter compression length than the compression length of typical fully pre-compressed springs. In several embodiments, the preload causes a compression length of the spring 234 that is less than 25 percent of the compression length of the fully compressed spring 234. In some embodiments, the preload causes a compression length of the spring 234 that is greater than 3 percent of the compression length of the fully compressed spring 234. The slight preload eliminates the "chatter" while having a force that is too small to cause substantial creep of non-spring components in the system.

[0373] The spring 234 can be inserted into the first portion 150 via a hole 238 in the proximal end of the first portion 150. Then, the needle hub 162 (and the attached C-shaped needle 156) can be loaded through the proximal side of the first portion 150 of the telescoping assembly (e.g., via the hole 238 in the proximal end of the first portion 150).

[0374] The needle hub 162 is slid through the first portion 150 until radial snaps (e.g., the release feature 160 of the needle hub 162) engage a section of the first portion 150 (see the latch 236). Thus, the spring 234 is placed with a slight preload between the needle hub 162 and a distal portion of the first portion 150 of the telescoping assembly 132.

[0375] During applicator activation and the telescoping (e.g., collapsing of the first portion 150 into the second portion 152), the spring 234 is compressed farther. At the bottom of travel (e.g., at the distal ending position), the radial snaps of the needle hub 162 are forced radially inward by features (e.g., the protrusions 170) in the telescoping assembly 132 (as shown

by the progression of Figures 7-11). This releases the needle hub 162 and allows the spring 234 to expand to drive the needle 156 proximally out of the host (and into the first portion 150 and/or the second portion 152).

[0376] As shown in figure 7, the base 128 protrudes from the distal end of the system while the first portion 150 of the telescoping assembly 132 is located in the proximal starting position and the glucose sensor 138 is located remotely relative to the base 128. The glucose sensor 138 is moveably coupled to the base 128 via the telescoping assembly 132 because the glucose sensor 138 is coupled to the first portion 150 and the base 128 is coupled to the second portion 152 of the telescoping assembly 132.

[0377] The system includes a spring 234 configured to retract a needle 156. The needle 156 is configured to facilitate inserting the glucose sensor 138 into the skin. In some embodiments, the system does not include the needle 156.

[0378] When the first portion 150 is in the proximal starting position, the spring 234 is in a first compressed state. The system is configured such that moving the first portion 150 distally from the proximal starting position increases a compression of the spring 234. The first compressed state places the first portion 150 and second portion 152 in tension. Latching features hold the first portion 150 and second portion 152 in tension. In other words, in the proximal starting position, the latching features are configured to prevent the spring 234 from pushing the first portion 150 proximally relative to the second portion 152. The latching features resist the first compressed state.

[0379] In several embodiments, the potential energy of the first compressed state is less than the amount of potential energy necessary to retract the needle 156. This low potential energy of the partially pre-compressed spring 234 is typically insufficient to cause creep, yet is typically sufficient to eliminate the "chatter" described above.

[0380] Redundant systems can help ensure that the needle 156 (and in some cases the sensor 138) can always be removed from the host after they are inserted into the host. If in extreme cases the necessary needle removal force is greater than the spring retraction force, the user can pull the entire telescoping assembly 132 proximally to remove the needle 156 and/or the sensor 138 from the host.

[0381] Some embodiments include a secondary retraction spring. In other words, in some embodiments, the spring 234 in Figure 7 is actually two concentric springs. (In several

embodiments, the spring 234 is actually just one spring.) The secondary spring can be shorter than the primary retraction spring. The secondary retraction spring can provide additional needle retraction force and can enable additional tailoring of the force profile.

[0382] Many users desire to minimize the amount of material they throw away (as trash). Moving the needle 156 to the back of the applicator post deployment enables easy access to remove the needle 156 post deployment.

[0383] Figure 20 illustrates a perspective view of the needle 156, the needle hub 162, and the spring 234 just after they were removed proximally from the hole 238 in a proximal end of the first portion 150 of the telescoping assembly 132.

[0384] The hole 238 is an opening at a proximal end of the applicator. The hole 238 is configured to enable removing the needle 156, the needle hub 162, and/or the spring 234. This opening can be covered by a removable cover (e.g., a sticker, a hinged lid).

[0385] Figures 21 and 22 illustrate perspective views where a removable cover 272 is coupled to the first portion 150 to cover the hole 238 through which the needle 156 can be removed from the telescoping assembly 132. A hinge 274 can couple the cover 272 to the first portion 150 such that the cover 272 can rotate to close the hole 238 (as shown in Figure 22) and rotate to open the hole 238 (as shown in Figure 21).

[0386] Removing the cover 272 can enable a user to remove the needle 156 from the applicator (e.g., the telescoping assembly 132) such that the user can throw the needle 156 in a sharps container and reuse the applicator with a new needle. Removing the needle 156 from the applicator can also enable throwing the rest of the applicator into a normal trash collector to reduce the amount of trash that needs to be held by the sharps container.

[0387] The features described in the context of Figures 20-22 and 60 can be combined with any of the embodiments described herein.

[0388] Figure 60 illustrates a perspective view of another telescoping assembly embodiment 132h. The cover 272h is adhered to a proximal end of the telescoping assembly 132h to cover a hole configured to retrieve a needle after the needle retracts (e.g., as described in the context of Figures 21 and 22). Peeling the cover 272h from the telescoping assembly 132h can enable a user to dump the needle 156 (shown in Figure 7) into a sharps container.

[0389] In this embodiment, the cover 272h is a flexible membrane such as a Tyvek label made by E. I. du Pont de Nemours and Company ("DuPont"). The cover 272h can include an adhesive to bond the cover 272h to the proximal end of the telescoping assembly 132h.

[0390] In some embodiments, a second cover 272 is adhered to a distal end of the telescoping assembly 132h to cover the end of the telescoping assembly 132h through which the sensor 138 (shown in Figure 7) passes. The distal end of the telescoping assembly 132h can also be covered by a plastic cap 122h.

[0391] The cover 272h can be configured to enable sterilization processes to pass through the material of the cover 272h to facilitate sterilization of the interior of the telescoping assembly 132h. For example, sterilization gases can pass through the cover 272h.

[0392] Any of the features described in the context of Figure 60 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figure 60 can be combined with the embodiments described in the context of Figures 1-59 and 61-70.

[0393] The telescoping assembly 132h can use the same interior features and components as described in the context of Figure 7. One important difference is that the first portion 150h slides on an outer surface of the second portion 152 (rather than sliding inside part of the second portion 152 as shown in Figure 7). Also, the telescoping assembly 132h does not use a sterile barrier shell 120 (as shown in Figure 2).

[0394] Any of the features described in the context of Figures 7-22 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 7-22 can be combined with the embodiments described in the context of Figures 23-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

FORCE PROFILES

[0395] Referring now to Figure 7, in some embodiments, moving the first portion 150 of the telescoping assembly 132 distally relative to the second portion 152 typically involves placing the distal end of the system against the skin of the host and then applying a distal force on the proximal end of the system. This distal force can cause the first portion 150 to move distally relative to the second portion 152 to deploy the needle 156 and/or the glucose sensor 138 into the skin.

[0396] The optimal user force generated axially in the direction of deployment is a balance between preventing accidental premature deployment and ease of insertion. A force that is ideal at a certain portion of distal actuation may be far less than ideal at another portion of distal actuation.

[0397] The user places the applicator (e.g., the telescoping assembly 132) against the skin surface and applies a force distally on the applicator (e.g., by pushing down on the proximal end of the applicator). When the user-generated force exceeds a threshold, the applicator collapses (e.g., telescopes distally) and the user drives the sensor into the body.

[0398] Several embodiments include unique force profiles that reduce accidental premature deployment; dramatically increase the likelihood of complete and proper deployment; and reduce patient discomfort. Specific structures enable these unique force profiles. For example, the following structures can enable the unique force profiles described herein: structures that hold the telescoping assembly 132 in the proximal starting position; structures that attach the sensor module 134 to the base 128; structures that release the sensor module 134 from the first portion 150; structures that prevent the needle 156 from retracting prematurely; structures that retract the needle 156; structures that release the base 128 from the second portion 152; structures that pad the collision at the distal position; and structures that hold the telescoping assembly 132 in a distal ending position. These structures are described in various sections herein.

[0399] Several embodiments include a system for applying an on-skin sensor assembly 600 to a skin 130 of a host (shown in Figure 4). Referring now to Figure 7, the system can comprise a telescoping assembly 132 having a first portion 150 configured to move distally relative to a second portion 152 from a proximal starting position to a distal position along a path 154; a glucose sensor 138 coupled to the first portion 150; and a latch 236 configurable to impede a needle 156 from moving proximally relative to the first portion.

[0400] The first portion 150 is releasably secured in the proximal starting position by a securing mechanism (e.g., the combination of 240 and 242 in Figure 7) that impedes moving the first portion 150 distally relative to the second portion 152. The system is configured such that prior to reaching the distal position and/or by reaching the distal position, moving the first portion 150 distally relative to the second portion 152 releases the latch 236 thereby causing the needle 156 to retract proximally into the system.

[0401] In several embodiments, the securing mechanism is formed by an interference between the first portion 150 and the second portion 152. The interference can be configured to impede the first portion 150 from moving distally relative to the second portion 152. For example, a radially outward protrusion 240 of the first portion 150 can collide with a proximal end 242 of the second portion 152 such that moving the first portion 150 distally requires overcoming a force threshold to cause the first portion 150 and/or the second portion 152 to deform to enable the radially outward protrusion 240 to move distally relative to the proximal end 242 of the second portion 152.

[0402] The system can include a first force profile measured along the path 154. As shown in Figure 23, the force profile 244 can include force on the Y axis and travel distance on the X axis. Referring now to Figures 7 and 23, the force profile 244 can be measured along the central axis 196.

[0403] One way in which the force profile 244 can be measured is to place the telescoping assembly 132 against the skin; place a force gauge such as a load cell on the proximal end of the telescoping assembly 132; calibrate the measurement system to account for the weight of the force gauge; and then press on the proximal side of the force gauge to drive the telescoping assembly 132 from the proximal starting position to the distal position along the path 154. Figure 23 illustrates force versus distance from the proximal starting position based on this type of testing procedure.

[0404] The first force profile 244 can comprise a first magnitude 246 coinciding with overcoming the securing mechanism (e.g., 240 and 242), a third magnitude 250 coinciding with releasing the latch 236 (e.g., releasing the needle retraction mechanism), and a second magnitude 248 coinciding with an intermediate portion of the path 154 that is distal relative to overcoming the securing mechanism and proximal relative to releasing the latch 236.

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[0405] In several embodiments, the second magnitude 248 is a peak force associated with compressing a needle retraction spring (e.g., the spring 234 in Figure 7) prior to beginning to release the latch 236. This peak force can be at least 0.5 pounds, at least 1.5 pounds, less than 4 pounds, and/or less than 6 pounds.

[0406] In several embodiments, the third magnitude 250 is a peak force associated with releasing the needle retraction mechanism. This peak force can be at least 1 pound, at least 2 pounds, less than 4 pounds, and/or less than 6 pounds.

[0407] In some embodiments, the second magnitude 248 is less than the first magnitude 246 and the third magnitude 250 such that the system is configured to promote needle acceleration during the intermediate portion of the path 154 to enable a suitable needle speed at a time the needle 156 (or the glucose sensor 138) first pierces the skin.

[0408] The first magnitude 246 can be the peak force required to overcome the securing mechanism (e.g., 240 and 242). This peak force can be at least 5 pounds, at least 6 pounds, less than 10 pounds, and/or less than 12 pounds. The first magnitude 246 can be at least 100 percent greater than the second magnitude 248. The first magnitude 246 can be at least 200 percent greater than the second magnitude 248. The second magnitude 248 can be during a portion of the force profile 244 where the compression of the spring 234 is at least 50 percent of the maximum spring compression reached just before the needle 156 begins to retract proximally. The slope of the force profile 244 can be positive for at least 1 millimeter during the time at which the second magnitude 248 is measured (due to the increasing spring force as the spring compression increases).

[0409] The first magnitude 246 can be greater than the third magnitude 250 (and/or greater than the second magnitude 248) such that the system is configured to impede initiating a glucose sensor insertion cycle unless a user is applying enough force to release the latch 236. For example, the force necessary for the protrusion 240 to move distally relative to the proximal end 242 can deliberately be designed to be greater than the force necessary to retract the needle 156.

[0410] To provide a sufficient safety margin, the first magnitude 246 can be at least 50 percent greater than the third magnitude 250. In some embodiments, the first magnitude 246 is at least 75 percent greater than the third magnitude 250. To avoid a system where the first magnitude 246 is unnecessarily high in light of the forces required along the path 154 distally

relative to the first magnitude 246, the first magnitude 246 can be less than 250 percent greater than the third magnitude 250.

[0411] A second force profile 252 can coincide with the intermediate portion of the path 154. For example, the second magnitude 248 can be part of the second force profile 252. This second force profile 252 can include a time period in which the slope is positive for at least 1 millimeter, at least 2.5 millimeters, less than 8 millimeters, and/or less than 15 millimeters (due to the increasing spring force as the spring compression increases).

[0412] A proximal millimeter of the second force profile 252 comprises a lower average force than a distal millimeter of the second force profile 252 in response to compressing a spring 234 configured to enable the system to retract the needle 156 into the telescoping assembly 132.

[0413] The system also includes a first force profile 254 (measured along the path 154). The first force profile 254 comprises a first average magnitude coinciding with moving distally past a proximal half of the securing mechanism and a second average magnitude coinciding with moving distally past a distal half of the securing mechanism. The first average magnitude is greater than the second average magnitude such that the system is configured to impede initiating a glucose sensor insertion cycle unless a user is applying enough force to complete the glucose sensor insertion cycle.

[0414] A first force peak 256 coincides with moving distally past the proximal half of the securing mechanism. The first force peak 256 is at least 25 percent higher than the second average magnitude.

[0415] The first force profile 254 comprises a first magnitude 246 coinciding with overcoming the securing mechanism and a subsequent magnitude coinciding with terminating the securing mechanism (e.g., moving past the distal portion of the securing mechanism). The first magnitude 246 comprises a proximal vector and the subsequent magnitude comprises a distal vector. Figure 23 is truncated at zero force, so the distal vector appears to be have a magnitude of zero in Figure 23, although the actual value is negative (e.g., negative 2 pounds).

[0416] The proximal vector means the system is resisting the distal movement of the first portion 150 relative to the second portion 152. The distal vector means that the second half of the securing mechanism can help propel the needle 156 and the sensor 138 towards the skin and/or into the skin. In other words, the distal vector assists the distal movement of the first portion 150 relative to the second portion 152.

[0417] The third force profile 260 can include many peaks and values due to the following events: the sensor module 134 docking to the base 128; the base detaching from the second portion 152 (and thus detaching from the telescoping assembly 132); the release feature 160 of the needle hub 162 defecting inward due to the proximal protrusions 170 of the second portion 152; the latch 236 releasing; the needle 156 retracting into an inner chamber of the first portion 150; and/or the first portion 150 hits the distal position (e.g., the end of travel).

[0418] As shown in Figure 7, the securing mechanism can be a radially outward protrusion 240 (of the first portion 150) configured to collide with a proximal end 242 of the second portion 152 such that moving the first portion 150 distally requires overcoming a force threshold to cause the first portion 150 and/or the second portion 152 to deform to enable the radially outward protrusion 240 to move distally relative to the proximal end 242 of the second portion 152. The radially outward protrusion 240 is configured to cause the second portion 152 to deform elliptically to enable the first portion 150 to move distally relative to the second portion 152.

[0419] Figure 24 illustrates another securing mechanism. At least a section of the first portion 150 interferes with a proximal end 242 of the second portion 152 such that pushing the first portion 150 distally relative to the second portion 152 requires a force greater than a force threshold. The force threshold is the minimum force necessary to deform at least one of the first portion 150 and the second portion 152 to overcome the interference 266, which is shown inside a dashed circle in Figure 24.

[0420] Many different interference geometries and types are used in various embodiments. The interference can be between the first portion 150 and the second portion 152. The interference can be between the needle hub 162 and the second portion 152. For example, the interference can resist the distal movement of the needle hub 162.

[0421] In some embodiments, the first portion 150 includes a taper 262. Once an interfering section of the first portion 150 moves distally past the interference area 266, the taper 262 makes the system such that the interference 266 no longer impedes distal movement of the first portion 150.

[0422] The second portion 152 can also have a taper 263. The taper 263 can be on an interior surface of the second portion 152 such that the interior size gets larger as measured proximally to distally along the taper 263.

[0423] The interfering portion 242 of the second portion 152 can include a ramp (as shown in Figure 24) to aid the deformation described above. The interfering section of the first portion 150 is located proximally relative to the interfering section of the second portion 152.

[0424] The securing mechanism can comprise a radially outward protrusion (e.g., 240 in Figure 7) of the first portion 150 that interferes with a radially inward protrusion of the second portion 152 (e.g., as shown by the interference 266 in Figure 24) such that the securing mechanism is configured to cause the second portion 152 to deform elliptically to enable the first portion 150 to move distally relative to the second portion 152.

[0425] Any of the features described in the context of Figures 24-32 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 24-32 can be combined with the embodiments described in the context of Figures 1-23 and 33-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0426] Figure 25 illustrates a cross sectional view of a portion of an embodiment in which the needle holder (e.g., the needle hub 162) is configured to resist distal movement of the first portion 150 relative to the second portion 152b. The second portion 152b is like other second portions 150 described herein (e.g., as shown in Figure 7) except that the second portion 152b includes flex arms 276 that are at least part of the securing mechanism. The flex arms 276 are releasably coupled to the needle holder to releasably secure the first portion 150 to the second portion 152b in the proximal starting position (as shown in Figure 7).

[0427] The needle 156 (shown in Figure 7) is retractably coupled to the first portion 150 by the needle holder 162. The needle holder 162 is configured to resist distal movement of the first portion 150 relative to the second portion 152b due to a chamfer and/or a ramp 278 interfering with flex arms 276. Pushing the first portion 150 distally requires overcoming the force necessary to deflect the flex arms 276 outward such that the flex arms 276 move out of the way of the ramp 278.

[0428] Figure 27 illustrates a perspective view of another securing mechanism, a frangible release 280. Figure 26 illustrates a top view of a frangible ring 282. The ring 282 includes two frangible tabs 284 that protrude radially inward. In some embodiments, the tabs 284 are radially inward protrusions on opposite sides of the ring 282 relative to each other. The frangible member (e.g., the ring 282) can be part of the first portion 150, the second portion 152, or any other portion of the system. For example, the frangible member can be a feature of a molded second portion 152.

[0429] The ring 282 can be made of a brittle material configured to enable the tabs 284 to break when the first portion 150 is pushed distally relative to the second portion 152. For example, a section of the first portion 150 can be located proximally over the tab 284 when the first portion 150 is in the proximal starting position (as shown in Figure 27 by the frangible release 280). Moving the first portion 150 distally can cause the section of the first portion 150 to bend and/or break the tab 284.

[0430] In some embodiments, a radially outward protrusion 286 of the first portion 150 is configured to bend and/or break the tab 284. The ring 282, the tab 284, and the other components described herein can be molded from a plastic such as acrylonitrile butadiene styrene, polyethylene, and polyether ether ketone. (Springs, interconnects, and needles can be made of steel.) In some embodiments, the ring 282 is at least 0.2 millimeters thick, at least 0.3 millimeters thick, less than 0.9 millimeters thick, and/or less than 1.5 millimeters thick.

[0431] The ring 282 can be secured between the first portion 150 and the second portion 152 of the telescoping assembly 132. The ring 282 can wrap around a perimeter of the first portion 150 and can be located proximally relative to the second portion 152 such that the ring 282 rests against a proximal end of the second portion 152.

[0432] The ring 282 enables a frangible coupling between the first portion 150 and the second portion 152 while the first portion 150 is in the proximal starting position. In Figure 27, the system is configured such that moving the first portion 150 to the distal position breaks the frangible coupling (e.g., the frangible release 280).

[0433] In some embodiments, the tabs 284 are not part of a ring 282. The tabs 284 can be part of the second portion 152 or part of the first portion 150.

[0434] Figure 27 also includes a magnet system 290. The magnet system 290 includes a magnet and a metal element in close enough proximity that the magnet is attracted to the metal

element (e.g., a metal disk). For example, the second portion 152 can include a magnet, and the first portion 150 can include the metal element. In several embodiments, the second portion 152 can include a metal element, and the first portion 150 can include the magnet.

[0435] The magnet and metal element can be located such that they are located along a straight line oriented radially outward from the central axis 196 (shown in Figure 7). This configuration can position the magnet for sufficient attraction to the metal element to resist movement of the first portion 150. For example, when the first portion 150 is in the proximal starting position, the magnetic force of the magnet system 290 can resist distal movement of the first portion. Thus, the magnet releasably couples the first portion 150 to the second portion 152 while the first portion 150 is in the proximal starting position.

[0436] In several embodiments, a user can compress an internal spring or the spring can be pre-compressed (e.g., compressed fully at the factory). The telescoping assembly can include a button 291 configured to release the spring force to cause the needle and/or the sensor to move into the skin.

[0437] The cover 272h described in the context of Figure 60 can be adhered to the proximal end of the first portion 150 shown in Figure 27. The cover 272h can be used with any of the embodiments described herein.

[0438] Figure 31 illustrates a side view of a telescoping assembly 132e having a first portion 150e and a second portion 152e. The first portion 150e includes a radially outward protrusion 286e configured to engage a radially inward ramp 296 located on an interior wall of the second portion 152e. When a user applies a distal, axial force on the first portion 150e, the protrusion 286e collides with the ramp 296. The angle of the ramp causes the first portion 150e to rotate relative to the second portion 152e. This rotation resists the distal force and acts as a securing mechanism. Once the protrusion 286e moves beyond the distal end of the ramp 296, the ramp 296 no longer causes rotation, and thus, no longer acts as a securing mechanism.

[0439] Many of the embodiments described herein rely on a compressive force of a person. Many unique structures enable the force profiles described herein. The structures help ensure the compressive force caused by a person pushing distally on a portion of the system results in reliable performance. One challenge of relying on people to push downward on the system to generation appropriate forces is that the input force can vary substantially by user. Even a single user can apply different input forces on different occasions.

[0440] One solution to this variability is to replace the need for a user-generated input force with a motor-generated force. The motor can provide reliable input forces. Motors also enable varying the force at different sections of the path from the proximal starting position to the distal position.

[0441] Figures 28-30 illustrates embodiments of telescoping assemblies 132c, 132d that include motors 290c, 290d to drive a needle 156 and/or a glucose sensor 138 into the skin. The motors 290c, 290d can be linear actuators that use an internal magnetic system to push a rod distally and proximally. The linear actuators can also convert a rotary input into linear motion to push a rod distally and proximally. The movement of the rod can move various portions of the system including the needle 156, the needle hub 162c, the first portion 150c, 150d of the telescoping assembly 132c, 132d, the sensor module 134, and/or the sensor 138. The motors 290c, 290d can include internal batteries to supply electricity for the motors 290c, 290d.

[0442] Figure 28 illustrates a perspective, cross-sectional view of an embodiment in which the motor 290c pushes the needle hub 162c distally relative to the motor 290c and relative to the second portion 152c. The needle hub 162c can include a rod that slides in and out of the housing of the motor 292c. The distal movement of the needle hub 162c can push at least a portion of the needle 156 and/or the sensor 138 (shown in Figure 7) into the skin. The distal movement of the needle hub 162c can move the sensor module 134 distally such that the sensor module 134 docks with the base 128. This coupling can precede the detachment of the base 128 from the telescoping assembly 132c.

[0443] Figures 29 and 30 illustrate side, cross-sectional views of another motor embodiment. In this embodiment, the rod 294 of the motor 292d is coupled to and immobile relative to the second portion 152d of the telescoping assembly 132d. The motor 292d is coupled to and immobile relative to the first portion 150d of the telescoping assembly 132d. As a result, pulling the rod 294 into the housing of the motor 292d causes the first portion 150d to move distally relative to the second portion 152d. The glucose module 134 is coupled to a distal portion of the first portion 150d (as described herein). Thus, the glucose sensor 138 is moved distally into the skin of the host and the glucose module 134 is coupled to the base 128. As illustrated in Figures 29 and 30, the embodiment does not include a needle. Similar embodiments can include a needle.

[0444] Figure 32 illustrates a perspective, cross-section view of the telescoping assembly 132. In some embodiments, a protrusion 302 of the first portion 150 couples with a hole 304 of the second portion 152. The protrusion 302 can be oriented distally to latch with the hole 304 in response to the first portion 150 reaching the distal position.

[0445] In several embodiments, a protrusion 302 of the second portion 152 couples with a hole 304 of the first portion 150. The protrusion 302 can be oriented proximally to latch with the hole 304 in response to the first portion 150 reaching the distal position.

[0446] The protrusion 302 can be a flex arm that is at least 10 millimeters long, at least 15 millimeters long, and/or less than 50 millimeters long. The protrusion 302 can include an end portion that protrudes at an angle relative to the central axis of the majority of the protrusion 302. This angle can be at least 45 degrees, at least 75 degrees, less than 110 degrees, and/or less than 135 degrees.

[0447] Coupling the protrusion 302 to the hole 304 can permanently lock the first portion 150 in a downward position (that is distal to the proximal starting position and is within 3 millimeter of the distal position) while the needle 156 is in a retracted state. This locking can prevent the system from being reused and can prevent needle-stick injuries.

[0448] Any of the features described in the context of Figure 23 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figure 23 can be combined with the embodiments described in the context of Figures 1-22 and 24-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

INTERCONNECTS

[0449] Referring now to Figure 4, in many embodiments, the electronic unit 500 drives a voltage bias through the sensor 138 so that current can be measured. Thus, the system is able to

analyze glucose levels in the host. The reliability of the electrical connection between the sensor 138 and the electronics unit 500 is critical for accurate sensor data measurement.

[0450] In many embodiments, the host or a caregiver create the electrical connection between the sensor 138 and the electronics unit 500. A seal 192 can prevent fluid ingress as the electronics unit 500 is pressed onto the glucose sensor module 134. Oxidation and corrosion can change electrical resistance of the system and are sources of error and noise in the signal.

[0451] The electrical connections should be mechanically stable. Relative movement between the parts of the electrical system can cause signal noise, which can hinder obtaining accurate glucose data.

[0452] A low-resistance electrical connection is more power efficient. Power efficiency can help maximize the battery life of the electronics unit 500.

[0453] In embodiments where the host or caregiver must compress the electrical interconnect and/or seal 192, minimizing the necessary force increase user satisfaction. Lowering the user-applied force makes the transmitter easier to install. If the necessary force is too great, users and caregivers may inadvertently fail to apply adequate force, which can jeopardize the reliability and performance of the system. The force that the user needs to apply to couple the electronics unit 500 to the base 128 and sensor module 134 is strongly influenced by the force necessary to compress the interconnect. Thus, there is a need for an electrical interconnect with a lower compression force.

[0454] Manufacturing variability, host movement, and temperature variations while the host is using the on-skin sensor assembly 600 necessitate providing a robust electrical connection throughout an active compression range (which encompasses the minimum and maximum compression states reasonably possible). Thus, there is a need for electrical connections that are tolerant of compression variation within the active compression range.

[0455] Metallic springs (e.g., coil or leaf springs) can be compressed between the sensor 138 and the electronics unit 500 to provide a robust, reliable electrical connection that requires a low compression force to couple the electronics unit 500 to the base 128.

[0456] Figure 33 illustrates a perspective view of an on-skin senor assembly just before the electronics unit 500 (e.g., a transmitter) is snapped onto the base 128. Coupling the electronics unit 500 to the base 128 can compress the seal 192 to prevent fluid ingress and can

compress an interconnect (e.g., springs 306) to create an electrical connection 310 between the glucose sensor 138 and the electronics unit 500.

[0457] Creating the electrical connection 310 and/or coupling the electronics unit 500 to the base 128 can cause the electronics unit 500 (e.g., a transmitter) to exit a sleep mode. For example, conductive members (e.g., of the sensor module 134 and/or of the base 128) can touch electrical contacts of the electronics unit 500 (e.g., electrical contacts of a battery of the electronics unit 500), which can cause the electronics unit 500 to exit a sleep mode. The conductive member of the sensor module 134 and/or of the base 128 can be a battery jumper that closes a circuit to enable electricity from the battery to flow into other portions of the electronics unit 500.

[0458] Thus, creating the electrical connection 310 and/or coupling the electronics unit 500 to the base 128 can "activate" the electronics unit 500 to enable and/or to prepare the electronics unit 500 to wirelessly transmit information to other devices 110-113 (shown in Figure 1). U.S. Patent Publication No. US-2012-0078071-A1 includes additional information regarding transmitter activation. The entire contents of U.S. Patent Publication No. US-2012-0078071-A1 are incorporated by reference herein.

[0459] The distal face of the electronics unit 500 can include planar electrical contacts that touch the proximal end portions of the springs 306. The distal end portions of the springs 306 can contact various conductive elements of the glucose sensor 138. Thus, the springs 306 can electrically couple the electronics unit 500 to the various conductive elements of the glucose sensor 138. In the illustrated embodiment, two metallic springs 306 electrically connect the glucose sensor 138 and the electronics unit 500. Some embodiments use one spring 306. Other embodiments use three, four, five, ten, or more springs 306.

[0460] Metallic springs 306 (e.g., gold-plated springs) are placed above the sensor wire 138 in the sensor module 134. The sensor 138 is located between a rigid polymer base 128 and the bottom surface of the spring 306. The top surface of the spring 306 contacts a palladium electrode located in the bottom of the electronics module 500. The rigid electronics module 500 and the rigid polymer base 128 are brought together creating a compressed sandwich with the sensor 138 and the spring 306.

[0461] The springs 306 can be oriented such that their central axes are within 25 degrees of the central axis 196 of the telescoping assembly 132 (shown in Figure 7). The springs 306 can have a helical shape. The springs 306 can be coil springs or leaf springs.

[0462] Springs 306 can have ends that are plain, ground, squared, squared and ground, or any other suitable configuration. Gold, copper, titanium, and bronze can be used to make the springs 306. Springs 306 can be made from spring steel. In several embodiments, the steels used to make the springs 306 can be low-alloy, medium-carbon steel or high-carbon steel with a very high yield strength. The springs 306 can be compression springs, torsion springs, constant springs, variable springs, helical springs, flat springs, machined springs, cantilever springs, volute springs, balance springs, leaf springs, V-springs, and/or washer springs.

[0463] Some embodiments use a spring-loaded pin system. The spring system can include a receptacle. A pin can be located partially inside the receptacle such that the pin can slide partially in and out of the receptacle. A spring can be located inside the receptacle such that the spring biases the pin outward towards the electronics unit 500. The receptacle can be electrically coupled to the sensor 138 such that pressing the electronics unit 500 onto the spring-loaded pin system electrically couples the electronics unit 500 and the sensor 138.

[0464] Mill-Max Mfg. Corp. of Oyster Bay, New York, U.S.A. ("Mill-Max") makes a spring-loaded pin system with a brass-alloy shell that is plated with gold over nickel. One Mill-Max spring-loaded pin system has a stainless steel spring and an ordering code of 0926-1-15-20-75-14-11-0.

[0465] In several embodiments, the electronics unit 500 includes a battery to provide electrical power to various electrical components (e.g., a transmitter) of the electronics unit 500.

[0466] In some embodiments, the base 128 can include a battery 314 that is located outside of the electronics unit 500. The battery 314 can be electrically coupled to the electrical connection 310 such that coupling the electronics unit 500 to the base 128 couples the battery 314 to the electronics unit 500. Figures 22B and 22C of U.S. Patent Publication No. US-2009-0076360-A1 illustrate a battery 444, which in some embodiments, can be part of the base (which can have many forms including the form of base 128 shown in Figure 33 herein). The entire contents of U.S. Patent Publication No. US-2009-0076360-A1 are incorporated by reference herein.

[0467] Figure 34 illustrates a perspective view of the sensor module 134. Protrusions 308 can secure the springs 306 to the sensor module 134. (Not all the protrusions 308 are labeled in order to increase the clarity of Figure 34.) The protrusions 308 can protrude distally.

[0468] At least three, at least four, and/or less than ten protrusions 308 can be configured to contact a perimeter of a spring 306. The protrusions 308 can be separated by gaps. The gaps enable the protrusions 308 to flex outward as the spring 306 is inserted between the protrusions 308. The downward force of coupling the electronics unit 500 to the base 128 can push the spring 306 against the sensor 138 to electrically couple the spring 306 to the sensor 138. The sensor 138 can run between at least two of the protrusions 308.

[0469] Figure 33 illustrates an on-skin sensor system 600 configured for transcutaneous glucose monitoring of a host. The on-skin sensor system 600 can be used with the other components shown in Figure 7. The sensor module 134 can be replaced with the sensor modules 134d, 134e shown in Figures 35 and 37. Thus, the sensor modules 134d, 134e shown in Figures 35 and 37 can be used with the other components shown in Figure 7.

[0470] Referring now to Figures 33 and 34, the system 600 can include a sensor module housing 312; a glucose sensor 138a, 138b having a first section 138a configured for subcutaneous sensing and a second section 138b mechanically coupled to the sensor module housing 312; and an electrical interconnect (e.g., the springs 306) mechanically coupled to the sensor module housing 312 and electrically coupled to the glucose sensor 138a, 138b. The springs can be conical springs, helical springs, or any other type of spring mentioned herein or suitable for electrical connections.

[0471] The sensor module housing 312 comprises at least two proximal protrusions 308 located around a perimeter of the spring 306. The proximal protrusions 308 are configured to help orient the spring 306. A segment of the glucose sensor 138b is located between the proximal protrusions 308 (distally to the spring 306).

[0472] The sensor module housing 312 is mechanically coupled to the base 128. The base 128 includes an adhesive 126 configured to couple the base 128 to skin of the host.

[0473] The proximal protrusions 308 orient the spring 306 such that coupling an electronics unit 500 to the base 128 presses the spring 306 against a first electrical contact of the electronics 500 unit and a second electrical contact of the glucose sensor 138b to electrically couple the glucose sensor 138a, 138b to the electronics unit 500.

[0474] Referring now to Figures 33 and 35-38, the system 600 can include a sensor module housing 312d, 312e; a glucose sensor 138a, 138b having a first section 138a configured for subcutaneous sensing and a second section 138b mechanically coupled to the sensor module housing 312d, 312e; and an electrical interconnect (e.g., the leaf springs 306d, 306e) mechanically coupled to the sensor module housing 312d, 312e and electrically coupled to the glucose sensor 138a, 138b. The sensor modules 134d, 134e can be used in place of the sensor module 134 shown in Figure 7. The leaf springs 306d, 306e can be configured to bend in response to the electronics unit 500 coupling with the base 128.

[0475] As used herein, cantilever springs are a type of leaf spring. As used herein, a leaf spring can be made of a number of strips of curved metal that are held together one above the other. As used herein in many embodiments, leaf springs only include one strip (e.g., one layer) of curved metal (rather than multiple layers of curved metal). For example, the leaf spring 306d in Figure 35 can be made of one layer of metal or multiple layers of metal. In some embodiments, leaf springs include one layer of flat metal secured at one end (such that the leaf spring is a cantilever spring).

[0476] As shown in Figures 35 and 36, the sensor module housing 312d comprises a proximal protrusion 320d having a channel 322d in which at least a portion of the second section of the glucose sensor 138b is located. The channel 322d positions a first area of the glucose sensor 138b such that the area is electrically coupled to the leaf spring 306d.

[0477] As shown in the cross-sectional, perspective view of Figure 36, the leaf spring 306d arcs away from the first area and protrudes proximally to electrically couple with an electronics unit 500 (shown in Figure 33). At least a portion of the leaf spring 306d forms a "W" shape. At least a portion of the leaf spring 306d forms a "C" shape. The leaf spring 306d bends around the proximal protrusion 320d. The leaf spring 306d protrudes proximally to electrically couple with an electronics unit 500 (shown in Figure 33). The seal 192 is configured to impede fluid ingress to the leaf spring 306d.

[0478] The leaf spring 306d is oriented such that coupling an electronics unit 500 to the base 128 (shown in Figure 33) presses the leaf spring 306d against a first electrical contact of the electronics unit 500 and a second electrical contact of the glucose sensor 138b to electrically couple the glucose sensor 138a, 138b to the electronics unit 500. The proximal height of the seal

192 is greater than a proximal height of the leaf spring 306d such that the electronics unit 500 contacts the seal 192 prior to contacting the leaf spring 306d.

[0479] Referring now to Figures 33 and 37-38, the sensor module housing 312e comprises a channel 322e in which at least a portion of the second section of the glucose sensor 138b is located. A distal portion of the leaf spring 306e is located in the channel 322e such that a proximal portion of the leaf spring 306e protrudes proximally out the channel 322e.

[0480] The sensor module housing 312e comprises a groove 326e that cuts across the channel 322e (e.g., intersects with the channel 322e). The leaf spring 306e comprises a tab 328 located in the groove to impede rotation of the leaf spring. At least a portion of the leaf spring 306e forms a "C" shape.

[0481] Figures 36 and 38 illustrate two leaf spring shapes. Other embodiments use other types of leaf springs. Elements shown in Figures 33-38 can be combined.

[0482] Referring now to Figures 33-38, interconnects 306, 306d, 306e can comprise a palladium contact, an alloy, a clad material, an electrically conductive plated material, gold plated portions, silver material, and/or any suitable conductor. Interconnects 306, 306d, 306e described herein can have a resistance of less than 5 ohms, less than 20 ohms, and/or less than 100 ohms. Many interconnect embodiments enable a resistance of approximately 2.7 ohms or less, which can significantly increase battery life compared to higher resistance alternatives.

[0483] Reducing the force necessary to compress an interconnect 306, 306d, 306e (e.g., as an electronics unit 500 is coupled to the base 128) can reduce coupling errors and difficulties. For example, if the necessary force is high, odds are substantial that users will inadvertently fail to securely couple the electronics unit 500 to the base 128. In some cases, if the necessary force is too high, some users will be unable to couple the electronics unit 500 to the base 128. Thus, there is a need for systems that require less force to couple the electronics unit 500 to the base 128.

[0484] Many embodiments described herein (e.g., spring embodiments) dramatically reduce the force necessary to couple the electronics unit 500 to the base 128. The interconnects 306, 306d, 306e can have a compression force of at least 0.05 pounds; less than 0.5 pounds, less than 1 pound, less than 3 pounds; and/or less than 4.5 pounds over an active compression range.

[0485] In some embodiments, the interconnects 306, 306d, 306e may require a compression force of less than one pound to compress the spring 20 percent from a relaxed

position, which is a substantially uncompressed position. In some embodiments, the interconnects 306, 306d, 306e may require a compression force of less than one pound to compress the spring 25 percent from a relaxed position, which is a substantially uncompressed position. In some embodiments, the interconnects 306, 306d, 306e may require a compression force of less than one pound to compress the spring 30 percent from a relaxed position, which is a substantially uncompressed position. In some embodiments, the interconnects 306, 306d, 306e change dependency to independent claim) may require a compression force of less than one pound to compress the spring 50 percent from a relaxed position, which is a substantially uncompressed position.

[0486] Springs 306, 306d, 306e can have a height of 2.6 millimeters, at least 0.5 millimeters, and/or less than 4 millimeters. The seal 192 can have a height of 2.0 millimeters, at least 1 millimeter, and/or less than 3 millimeters. In some embodiments, in their relaxed state (i.e., a substantially uncompressed state), springs 306, 306d, 306e protrude (e.g., distally) at least 0.2 millimeters and/or less than 1.2 millimeters from the top of the seal 192.

[0487] When the electronics unit 500 is coupled to the base 128, the compression of the springs 306, 306d, 306e can be 0.62 millimeters, at least 0.2 millimeters, less than 1 millimeter, and/or less than 2 millimeters with a percent compression of 24 percent, at least 10 percent, and/or less than 50 percent. Active compression range of the springs 306, 306d, 306e can be 16 to 40 percent, 8 to 32 percent, 40 to 57 percent, 29 to 47 percent, at least 5 percent, at least 10 percent, and/or less than 66 percent.

[0488] In some embodiments, the electrical connection between the sensor 138 and the electronics unit 500 is created at the factory. This electrical connection can be sealed at the factory to prevent fluid ingress, which can jeopardize the integrity of the electrical connection.

[0489] The electrical connection can be made via any of the following approaches: An electrode can pierce a conductive elastomer (such that vertical deformation is not necessary); the sensor can be "sandwiched" (e.g., compressed) between adjacent coils of a coil spring; conductive epoxy; brazing; laser welding; and resistance welding.

[0490] Referring now to Figures 4, 6, 7, and 33, one key electrical connection is between the electronics unit 500 (e.g., a transmitter) and the sensor module 134. Another key electrical connection is between the sensor module 134 and the glucose sensor 138. Both connections should be robust to enable connecting the sensor module 134 to the base 128, and then

connecting the base 128 and sensor module 134 to the electronics unit 500 (e.g., a transmitter). A stable sensor module 134 allows the sensor module 134 to couple to the base 128 without causing signal noise in the future.

[0491] These two key electrical connections can be made at the factory (e.g., prior to the host or caregiver receiving the system). These electrical connections can also be made by the host or caregiver when the user attaches the electronics unit 500 to the base 128 and/or the sensor module 134.

[0492] In some embodiments, the connection between the glucose sensor 138 and the sensor module 134 can be made at the factory (e.g., prior to the user receiving the system), and then the user can couple the electronics unit 500 to the sensor module 134 and/or the base 128. In several embodiments, the electronics unit 500 can be coupled to the sensor module 134 and/or to the base 128 at the factory (e.g., prior to the user receiving the system), and then the user can couple this assembly to the glucose sensor 138.

[0493] Any of the features described in the context of Figures 33-38 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 33-38 can be combined with the embodiments described in the context of Figures 1-32 and 39-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0494] Referring now to Figure 33, the battery 314 can be located inside the electronics unit 500 or can be part of the base 128. Maximizing the life of the battery 314 is important to many reasons. For example, the electronics unit 500 may be in storage for months or even years before it is used. If the battery 413 is substantially depleted during this storage, the number of days that a host can use the electronics unit (e.g., to measure an analyte) can be dramatically diminished.

[0495] In some embodiments, the electronics unit 500 is in a low-power-consumption state (e.g., a "sleep" mode) during storage (e.g., prior to being received by the host). This low-

power-consumption state can drain the battery 314. Thus, there is a need for a system that reduces or even eliminates battery power consumption during storage and/or prior to the electronics unit 500 being coupled to the base 128.

[0496] As described in the context of Figure 33, creating the electrical connection 310 and/or coupling the electronics unit 500 to the base 128 can cause the electronics unit 500 (e.g., a transmitter) to exit a sleep mode. For example, conductive members (e.g., of the sensor module 134 and/or of the base 128) can touch electrical contacts of the electronics unit 500 (e.g., electrical contacts of a battery of the electronics unit 500), which can cause the electronics unit 500 to exit a sleep mode and/or can begin the flow of electrical power from the battery. The conductive member of the sensor module 134 and/or of the base 128 can be a battery jumper that closes a circuit to enable electricity from the battery to flow into other portions of the electronics unit 500.

[0497] Thus, creating the electrical connection 310 and/or coupling the electronics unit 500 to the base 128 can "activate" the electronics unit 500 to enable and/or to prepare the electronics unit 500 to wirelessly transmit information to other devices 110-113 (shown in Figure 1). U.S. Patent Publication No. US-2012-0078071-A1 includes additional information regarding electronics unit 500 activation (e.g., transmitter activation). The entire contents of U.S. Patent Publication No. US-2012-0078071-A1 are incorporated by reference herein.

[0498] Figure 65 illustrates a perspective view of portions of a sensor module 134j. Some items, such as springs and sensors, are hidden in Figure 65 to clarify that the sensor module 134j can use any spring or sensor described herein. The sensor module 134j can use any of the springs 306, 306d, 306e; sensors 138, 138a, 138b; protrusions 308; channels 322d, 322e; and grooves 326e described herein (e.g., as shown in Figures 34-40). The sensor module 134j can be used in the place of any other sensor module described herein. The sensor module 134j can be used in the embodiment described in the context of Figure 7 and can be used with any of the telescoping assemblies described herein.

[0499] Figure 66 illustrates a cross-sectional side view of the sensor module shown in Figure 65. Referring now to Figures 65-70, the sensor module 134j includes a conductive jumper 420f (e.g., a conductive connection that can comprise metal). The conductive jumper 420f is configured to electrically couple two electrical contacts 428a, 428b of the electronics unit

500 (e.g., a transmitter) in response to coupling the electronics unit 500 to the sensor module 134j and/or to the base 128.

[0500] The conductive jumper 420f can be located at least partially between two electrical connections 426 (e.g., springs 306, 306d, 306e shown in Figures 34-38). The conductive jumper 306f can include two springs 306f coupled by a conductive link 422f. A first spring 306f of the jumper 420f can be coupled to a first contact 428a, and a second spring 306f of the jumper 420f can be coupled to a second contact 428b, which can complete an electrical circuit to enable the battery to provide electricity to the electronics unit 500. The springs 306f can be leaf springs, coil springs, conical springs, and/or any other suitable type of spring. In some embodiments, the springs 306f are proximal protrusions that are coupled with the contacts 428a, 428b.

[0501] As shown in Figure 66, the conductive link 422f can be arched such that a sensor 138b (shown in Figure 34) passes under and/or through the arched portion of the conductive link 422f. In several embodiments, the conductive link 422f is oriented within plus or minus 35 degrees of perpendicular to the sensor 138b such that the conductive link 422f crosses over the portion of the sensor 138b that is located inside the seal area (e.g., within the interior of the seal 192).

[0502] Figure 67 illustrates a perspective view of portions of a sensor module 134k that is similar to the sensor module 134j shown in Figures 65 and 66. Figure 68 illustrates a top view of the sensor module 134k shown in Figure 67.

[0503] Referring now to Figures 67 and 68, the sensor module 134k includes a different type of conductive jumper 420g, which includes two helical springs 306g conductively coupled by a conductive link 422g. The conductive link 422g is configured to cross over or under the sensor 138b (shown in Figure 34). As shown in Figures 67 and 68, the springs 306g are conical springs, however, some embodiments do not use conical springs. The springs 306g are configured to electrically couple two electrical contacts 428a, 428b of the electronics unit 500 to start the flow the electricity within the electronics unit 500. Thus, the conductive jumper 420g can "activate" the electronics unit 500. The conductive jumper 420g can be used with any of the sensor modules described herein.

[0504] Figures 69 and 70 illustrate perspective views of an electronics unit 500 just before the electronics unit 500 is coupled to a base 128. As shown in Figure 70, the electronics

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unit 500 can have two electrical contacts 428a, 428b configured to be electrically coupled to a conductive jumper 420f (shown in Figures 65 and 66), 420g (shown in Figures 67 and 68). The electronics unit 500 can also have two electrical contacts 428c, 428d configured to be electrically coupled to the springs 306, 306d, 306e (shown in Figures 34-38) and/or to any other type of electrical connection 426 between the sensor 138 (shown in Figure 39) and the electronics unit 500.

[0505] Coupling the electronics unit 500 to the sensor module 134k and/or to the base 128 can electrically and/or mechanically couple the electrical contacts 428a, 428b to the conductive jumper 420f (shown in Figure 65), 420g (shown in Figure 67).

[0506] Coupling the electronics unit 500 to the sensor module 134k and/or to the base 128 can electrically and/or mechanically couple the electrical contacts 428c, 428d to the springs 306, 306d, 306e (shown in Figures 34-38) and/or to any other type of electrical connection 426 (e.g., as shown in Figure 67) between the sensor 138 (shown in Figure 39) and the electronics unit 500.

[0507] Any of the features described in the context of Figures 65-70 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 65-70 can be combined with the embodiments described in the context of Figures 1-64. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

NEEDLE ANGLE AND OFFSET

[0508] Figure 43 shows a front view of a "C-shaped" needle 156. Figure 42 illustrates a bottom view of the C-shaped needle 156. The needle 156 includes a channel 330. A section 138a (shown in Figure 34) of the glucose sensor 138 (labeled in Figure 7) that is configured for subcutaneous sensing can be placed in the channel 330 (as shown in Figure 40).

[0509] The needle 156 can guide the sensor 138 into the skin of the host. A distal portion of the sensor 138 can be located in the channel 330 of the needle 156. Sometimes, a distal end of

the sensor 138 sticks out of the needle 156 and gets caught on tissue of the host as the sensor 138 and needle 156 are inserted into the host. As a result, the sensor 138 may buckle and fail to be inserted deeply enough into the subcutaneous tissue. In other words, in some embodiments, the sensor wire must be placed within the channel 330 of the C-shaped needle 156 to be guided into the tissue and must be retained in the channel 330 during deployment.

[0510] The risk of the sensor 138 sticking out of the channel 330 (and thereby failing to be property inserted into the host) can be greatly diminished by placing the sensor 138 in the channel 330 of the needle 156 with a particular angle 338 (shown in Figure 41) and offset 336 (shown in Figure 40. Position B 334 in Figure 42 illustrates a sensor sticking out of the channel 330.

[0511] The angle 338 and offset 336 cause elastic deformation of the sensor 138 to create a force that pushes the sensor 138 to the bottom of the channel 300 (as shown by position A 332 in Figure 42) while avoiding potentially detrimental effects of improper angles 338 and offset 336. The angle 338 and offset 336 can also cause plastic deformation of the sensor 138 to help shape the sensor 138 in a way that minimizes the risk of the sensor 138 being dislodged from the channel 330 during insertion into the skin.

[0512] In several embodiments, the angle 338 and offset 336 shape portions of the sensor 138 for optimal insertion performance. For example, the angle 338 can bend the sensor 138 prior to placing portions of the sensor 138 in the channel 330 of the needle 156.

[0513] As illustrated in Figure 39, a portion of the glucose sensor 138b (also labeled in Figure 34) can be placed in a distally facing channel 342 (which, in some embodiments, is a tunnel). This channel 342 can help orient the glucose sensor 138b towards the channel 330 of the needle 156 (shown in Figure 43).

[0514] As illustrated in Figure 41, the glucose sensor 138 can include an angle 338 between a portion of the glucose sensor 138 that is coupled to the sensor module housing 312 (shown in Figure 34) and a portion of the glucose sensor that is configured to be inserted into the host. In some embodiments, this angle 338 can be formed prior to coupling the sensor 138 to the sensor module house 312 (shown in Figure 34) and/or prior to placing a portion of the sensor 138 in the channel 330 of the needle 156 (shown in Figure 43).

[0515] Referring now to Figure 41, an angle 338 that is less than 110 degrees can result in deployment failures (e.g., with an offset of 0.06 inches plus 0.06 inches and/or minus 0.03

inches). In some embodiments, an angle 338 that is less than 125 degrees can result in deployment failures (e.g., with an offset of 0.06 inches plus 0.06 inches and/or minus 0.03 inches). An angle 338 of 145 degrees (plus 5 degrees and/or minus 10 degrees) can reduce the probability of deployment failures. In some embodiments, the angle 338 is at least 120 degrees and/or less than 155 degrees.

[0516] In some embodiments, a manufacturing method includes bending the sensor 138 prior to placing portions of the sensor 138 in the channel 330 of the needle 156. In this manufacturing method, an angle is measured from a central axis of a portion of the glucose sensor 138 that is coupled to the sensor module housing 312 (shown in Figure 34) and a portion of the glucose sensor that is configured to be inserted into the needle. According to this angle measurement, an angle that is greater than 70 degrees can result in deployment failures (e.g., with an offset of 0.06 inches plus 0.06 inches and/or minus 0.03 inches). In some embodiments, an angle that is greater than 55 degrees can result in deployment failures (e.g., with an offset of 0.06 inches plus 0.06 inches and/or minus 0.03 inches). An angle of 35 degrees (plus 10 degrees and/or minus 5 degrees) can reduce the probability of deployment failures. In some embodiments, the angle is at least 25 degrees and/or less than 60 degrees.

[0517] An offset 336 (shown in Figure 40) that is too large can result in the sensor 138 not being reliably held in the channel 330 (shown in Figure 42). In other words, a large offset 336 can result in the sensor 138 being located in position B 334 rather than securely in position A 332. An offset 336 that is too small can place too much stress on the sensor 138, which can break the sensor 138. In light of these factors, in several embodiments, the offset 336 is at least 0.02 inches, at least 0.04 inches, less than 0.08 inches, and/or less than 0.13 inches. In some embodiments, the offset 336 is equal to or greater than 0.06 inches and/or less than or equal to 0.10 inches. The offset 336 is measured as shown in Figure 40 from the root of the needle 156.

[0518] In some embodiments, at least a portion of the bend of the sensor 138 can include a strain relief. For example, the bend of the sensor 138 can be encapsulated in a polymeric tube or an elastomeric tube to provide strain relief for the sensor 138. In some instances, the entire bend of the sensor 138 can be encapsulated in a polymeric tube or an elastomeric tube. In some embodiments, the tube is composed of a soft polymer. The polymeric tube or elastomeric tube can encapsulate the sensor 138 by a heat shrink process. In some embodiments, a silicone gel

may be applied to the sensor at or near channel 342 (shown in FIG. 39), or along at least a portion of the underside of proximal protrusion 320d (shown in FIG. 35).

[0519] The needle channel width 344 (shown in Figure 42) can be 0.012 inches. In some embodiments, the width 344 is equal to or greater than 0.010 inches and/or less than or equal to 0.015 inches. The width 344 of the channel 330 is measured at the narrowest span in which the glucose sensor 138 could be located.

[0520] Referring now to Figure 40, a funnel 182 in the base 128 can help guide the needle 156 and/or the glucose sensor 138 into the hole 180. The funnel 182 and the hole 180 can help secure the sensor 138 in the C-shaped needle 156 during storage and deployment. For example, the hole 180 can be so small that there is not extra room (within the hole 180) for the sensor 138 to exit the channel 330 (shown in Figure 42) of the needle 156.

[0521] Another role of the funnel 182 and hole 180 is to support the needle 156 and/or the sensor 138 against buckling forces during insertion of the needle 156 and/or the sensor 138 into the host.

[0522] The funnel 182 and the hole 180 also protect against inadvertent needle-stick injuries (because they are too small to enable, for example, a finger to reach the needle 156 prior to needle deployment).

[0523] The sensor module 134 is unable to pass through the funnel 182 and hole 180 (e.g., due to the geometries of the sensor module 134 and the funnel 182). Preventing the sensor module 134 from passing through the base 128 ensures the sensor module 134 is removed from the host's body when the base 128 is detached from the host. The angle 338 can prevent all of the sensor 138 from passing through the hole 180 to ensure the sensor 138 is removed from the host's body when the base 128 is detached from the host.

[0524] Any of the features described in the context of Figures 39-43 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 39-43 can be combined with the embodiments described in the context of Figures 1-38 and 44-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or

embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

NEEDLE-FREE

[0525] Some embodiments use a needle to help insert a glucose sensor into subcutaneous tissue. Some people, however, are fearful of needles. In addition, needle disposal can require using a sharps container, which may not be readily available.

[0526] Many embodiments do not use a needle to insert the sensor, which can help people feel more comfortable inserting the sensor and can eliminate the need to use a sharps container to dispose of the applicator or portions thereof.

[0527] U.S. Patent Publication No. US-2011-0077490-A1, U.S. Patent Publication No. US-2014-0107450-A1, and U.S. Patent Publication No. US-2014-0213866-A1 describe several needle-free embodiments. The entire contents of U.S. Patent Publication No. US-2011-0077490-A1, U.S. Patent Publication No. US-2014-0107450-A1, and U.S. Patent Publication No. US-2014-0213866-A1 are incorporated by reference herein.

[0528] Any of the embodiments described herein can be used with or without a needle. For example, the embodiments described in the context of Figures 1-50 can be used with or without a needle. For example, the embodiment shown in Figure 7 can be used in a very similar way without the needle 156. In this needle-free embodiment, moving the first portion 150 distally drives a distal portion of the glucose sensor 138 into the skin (without the use of a needle 156). In needle-free embodiments, the sensor 138 can have sufficient buckling resistance such that (when supported by the hole 180) the sensor 138 does not buckle. Sharpening a distal tip of the sensor 138 can also facilitate needle-free insertion into the host.

[0529] Figure 56 illustrates an embodiment very similar to the embodiment shown in Figure 7 except that the embodiment of Figure 56 does not include a needle. The telescoping assembly 132b pushes the sensor 138 (which can be any type of analyte sensor) into the body of the host. The embodiment shown in Figure 56 does not include a needle hub 162, a spring 234, or a needle retraction mechanism 158 (as shown in Figure 7) but can include any of the items and features described in the context of other embodiments herein.

[0530] Figure 57 illustrates the first portion 150 moving distally relative to the second portion 152 of the telescoping assembly 132b to move the sensor module 134 and the sensor 138

towards the base 128 in preparation to couple the sensor module 134 and the sensor 138 to the base 128.

[0531] Figure 58 illustrates the first portion 150 in a distal ending position relative to the second portion 152. The sensor module 134 and the sensor 138 are coupled to the base 128. The base 128 is no longer coupled to the telescoping assembly 132b such that the telescoping assembly 132b can be discarded while leaving the adhesive 126 coupled to the skin of the host (as described in the context of Figures 4-6).

[0532] The embodiment illustrated in Figures 56-58 can be integrated into the applicator system 104 shown in Figures 2 and 3.

[0533] The items and features described in the context of Figures 12A-50 can also be used with the embodiment illustrated in Figures 56-58. Items and features are described in the context of certain embodiments to reduce redundancy. The items and features shown in all the drawings, however, can be combined. The embodiments described herein have been designed to illustrate the interchangeability of the items and features described herein.

[0534] Figures 44 and 45 illustrate another embodiment of a telescoping assembly 132g. This embodiment includes a first portion 150g that moves distally relative to a second portion 152g to push a glucose sensor 138g through a hole in a base 128g and into a host.

[0535] The first portion 150g (e.g., a pusher) of the telescoping assembly 132g can include a distal protrusion 352 that supports a substantially horizontal section of the glucose sensor 138g (e.g., as the glucose sensor 138g protrudes out from the sensor module 134g). The end of the distal protrusion 352 can include a groove 354 in which at least a portion of the glucose sensor 138g is located. The groove 354 can help retain the glucose sensor 138g. The distal protrusion 352 can provide axial support to the glucose sensor 138g (e.g., to push the glucose sensor 138g distally into the tissue of the host).

[0536] The base 128g can include a funnel 182g that faces proximally to help guide a distal end of the glucose sensor 138g into a hole 180g in the base 128g. The hole 180g can radially support the sensor 138g as the sensor 138g is inserted into the tissue of the host.

[0537] When the first portion 150g of the telescoping assembly 132g is in the proximal starting position, the distal end of the glucose sensor 138g can be located in the hole 180g to help guide the glucose sensor 138g in the proper distal direction.

[0538] The hole 180g can exit a convex distal protrusion 174g in the base 128g. The convex distal protrusion 174g can help tension the skin prior to sensor insertion. As described more fully in other embodiments, the base 128g can rest against the skin of the host as the sensor module 134g moves distally towards the base 128g and then is coupled to the base 128g.

[0539] The telescoping assembly 132g (e.g., an applicator) does not include a needle. As a result, there is no sharp in the applicator, which eliminates any need for post-use sharp protection. This design trait precludes a need for a retraction spring or needle hub. The distal end of the sensor wire 138g can be sharpened to a point to mitigate a need for an insertion needle.

[0540] The telescoping assembly 132g (e.g., an applicator) can include the first portion 150g and the second portion 152g. The base 128g can be coupled to a distal end of the first portion 150g. The glucose sensor 138g and the sensor module 134g can be coupled to a distal end of the first portion 150g such that he applicator does not require a spring, needle, or needle hub; the first portion 150g is secured in a proximal starting position by an interference between the first portion 150g and the second portion 152g of the telescoping assembly 132g; and/or applying a distal force that is greater than a breakaway threshold of the interference causes the first portion 150g to move distally relative to the second portion 152g (e.g., until the sensor 138g is inserted into the tissue and the sensor module 134g is coupled to the base 128g).

[0541] Figures 46 and 47 illustrate a similar needle-free embodiment. This embodiment does not use the distal protrusion 352 shown in Figure 45. Instead, the sensor module 134h includes a distally oriented channel 358 that directs the sensor 138h distally such that the glucose sensor 138h includes a bend that is at least 45 degrees and/or less than 135 degrees. A channel cover 362 secures the glucose sensor 138h in the distally oriented channel 358.

[0542] The embodiments illustrated in Figures 44-47 can be integrated into the applicator system 104 shown in Figures 2 and 3. Referring now to Figure 2, the electronics unit 500 (e.g., a transmitter having a battery) can be detachably coupled to the sterile barrier shell 120. The rest of the applicator system 104 can be sterilized, and then the electronics unit 500 can be coupled to the sterile barrier shell 120 (such that the electronics unit 500 is not sterilized with the rest of the applicator system 104).

[0543] The items and features described in the context of Figures 12A-43 and 48-70 can also be used with the embodiments illustrated in Figures 44-47. Items and features are described

in the context of certain embodiments to reduce redundancy. The items and features shown in all the drawings, however, can be combined. The embodiments described herein have been designed to illustrate the interchangeability of the items and features described herein.

[0544] Any of the features described in the context of Figures 44-47 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 44-47 can be combined with the embodiments described in the context of Figures 1-43 and 48-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0545] In some embodiments, the sensor 138 can be deployed (e.g., into the skin of the host) in response to coupling the electronics unit 500 (e.g., a transmitter) to the base 128. The sensor 138 can be any type of analyte sensor (e.g., a glucose sensor).

[0546] Premature deployment of the sensor 138 can cause insertion of the sensor 138 into the wrong person and/or insufficient sensor insertion depth. Premature deployment can also damage the sensor 138, which in some embodiments, can be fragile. Thus, there is a need to reduce the likelihood of premature sensor deployment.

[0547] One way to reduce the likelihood of premature sensor deployment is for the system to include an initial resistance (e.g., to coupling the electronics unit 500 to the base 128). The initial resistance can necessitate a force buildup prior to overcoming the initial resistance. When the initial resistance is overcome, the sensor 138 is typically deployed faster than would be the case without an initial resistance (e.g., due to the force buildup, which can be at least 0.5 pounds, 1 pound, and/or less than 5 pounds). This fast deployment can reduce pain associated with the sensor insertion process.

[0548] In some embodiments, the resistance to coupling the electronics unit 500 to the base 128 after overcoming the initial resistance is less than 10 percent of the initial resistance, less than 40 percent of the initial resistance, and/or at least 5 percent of the initial resistance. Having a low resistance to coupling the electronics unit 500 to the base 128 after overcoming the

initial resistance can enable fast sensor insertion, which can reduce the pain associated with the sensor insertion process.

[0549] Figures 56-58 illustrate the first portion 150 deploying the sensor 138 into the skin of the host. In some embodiments, the first portion 150 is replaced with the electronics unit 500 shown in Figure 4 such that coupling the electronics unit 500 to the base 128 pushes the sensor 138 into the skin of the host. Referring now to Figures 4 and 56-58, the protrusion 240 (as explained in other embodiments) can be a portion of the electronics unit 500 such that moving the electronics unit distally relative to the second portion 152 and/or coupling the electronics unit 500 to the base 128 requires overcoming the initial resistance of the protrusion 240.

[0550] In some embodiments configured such that the sensor 138 is deployed (e.g., into the skin of the host) in response to coupling the electronics unit 500 to the base 128, a telescoping assembly 132b is not used. Instead, features of the base 128 provide the initial resistance to coupling the electronics unit 500 to the base 128. Although the locking feature 230 in Figure 33 is used for different purposes in some other embodiments, the locking feature 230 of the base 128 can couple with a corresponding feature of the electronics unit 500. This coupling can require overcoming an initial resistance.

[0551] Any of the features and embodiments described in the context of Figures 1-70 can be applicable to all aspects and embodiments in which the sensor 138 is deployed (e.g., into the skin of the host) in response to coupling the electronics unit 500 (e.g., a transmitter) to the base 128.

VERTICAL LOCKING

[0552] After a telescoping assembly (e.g., an applicator) has been used to insert a glucose sensor, the needle used to insert the glucose sensor could inadvertently penetrate another person. To guard against this risk, the telescoping assembly can protect people from subsequent needle-stick injuries by preventing the first portion of the telescoping assembly from moving distally relative to the second portion after the sensor has been inserted into the host.

[0553] Figure 48 illustrates a perspective, cross-sectional view of a telescoping assembly 132i that includes a first portion 150i and a second portion 152i. Referring now to Figures 48-50, the first portion 150i is configured to telescope distally relative to the second portion 152i. The second portion 152i of the telescoping assembly 132i can include a proximal protrusion 364

that can slide past a lock-out feature 366 of the first portion 150i of the telescoping assembly 132i as the first portion 150i is moved distally.

[0554] The proximal protrusion 364 can be biased such that elastic deformation of the proximal protrusion 364 creates a force configured to press the proximal protrusion 364 into the bottom of the lock-out feature 366 once the proximal protrusion 364 engages the lock-out feature 366.

[0555] The proximal protrusion 364 does not catch on the lock-out feature 366 as the first portion 150i moves distally a first time. Once the first portion 150i is in a distal ending position, a spring can push the first portion 150i to a second proximal position. Rather than returning to the starting proximal position, the proximal protrusion 364 catches on the lock-out feature 366 (due to the bias of the proximal protrusion 364 and the distally facing notch 368 of the lock-out feature 366).

[0556] Once a proximal end of the proximal protrusion 364 is captured in the lock-out feature 366, the rigidity of the proximal protrusion 364 prevents the first portion 150i of the telescoping assembly 132i from moving distally a second time.

[0557] As the first portion 150i moves distally relative to the second portion 152i, a ramp 370 of the first portion 150i pushes the proximal protrusion 364 outward (towards the lock-out feature 366). The proximal protrusion 364 can be located between two distal protrusions 372 of the first portion 150i. The distal protrusions 372 can guide the proximal protrusion 364 along the ramp 370.

[0558] As a portion of the proximal protrusion 364 slides along the ramp 370 (as the first portion 150i moves distally), the ramp bends the proximal protrusion 364 until a portion of the proximal protrusion 364 that was previously between the two distal protrusions 372 is no longer between the distal protrusions 372. Once the portion of the proximal protrusion 364 is no longer between the two distal protrusions 372, the proximal protrusion 364 is in a state to catch on the notch 368. The notch 368 can be part of the distal protrusions 372.

[0559] The second portion 152i of the telescoping assembly 132i can include a proximal protrusion 364, which can be oriented at an angle between zero and 45 degrees relative to a central axis). The first portion 150i of the telescoping assembly 132i can include features that cause the proximal protrusion 364 to follow a first path as the first portion 150i moves distally and then to follow a second path as the first portion 150i moves proximally. The second path

includes a locking feature 366 that prevents the first portion 150i from moving distally a second time.

[0560] The first portion 150i can include a ramp 370 that guides the proximal protrusion 364 along the first path. A distal protrusion (e.g., the ramp 370) of the first portion 150i can bias the proximal protrusion 364 to cause the proximal protrusion 364 to enter the second path as the first portion 150i moves proximally. The proximal protrusion 364 can be a flex arm. The lock 366 can comprise a distally facing notch 368 that catches on a proximal end of the proximal protrusion 364.

[0561] As shown in Figures 48 and 50, the telescoping assembly 132i can include a sensor module 134i. The sensor module 134i can be any of the sensor modules described herein.

[0562] Any of the features described in the context of Figures 48-50 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 48-50 can be combined with the embodiments described in the context of Figures 1-47 and 51-70. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

DUAL-SPRING ASSEMBLY

[0563] Partial sensor insertion can lead to suboptimal sensing. In some cases, partial sensor insertion can create a needle-stick hazard (due to the needle not retracting into a protective housing). Thus, there is a need for systems that ensure full sensor insertion.

[0564] The embodiment illustrated in Figures 61-64 dramatically reduces the odds of partial sensor insertion by precluding sensor insertion until sufficient potential energy is stored in the system. The potential energy is stored in a first spring 402.

[0565] The system includes many items from the embodiment illustrated in Figure 7 (e.g., the base 128 and the sensor module 134). The system includes an optional needle 156 and needle hub 162. The embodiment illustrated in Figures 61-64 can also be configured to be

needle-free by removing the needle 156, the second spring 234, the needle hub 162, and the needle retraction mechanism 158.

[0566] The telescoping assembly 132k has three portions 150k, 152k, 392. Moving the third portion 392 distally relative to the second portion 152k stores energy in the first spring 402 (by compressing the first spring 402). Once the first portion 150k is unlocked from the second portion 152k, the energy stored in the compressed first spring 402 is used to push the first portion 150k distally relative to the second portion 152k to drive the sensor 138 (shown in Figure 7) into the skin of the host.

[0567] To ensure the first portion 150k does not move distally relative to the second portion 152k until the first spring 402 is sufficiently compressed (and thus has enough stored energy), the first portion 150k is locked to the second portion 152k. Once the first spring 402 is sufficiently compressed (and thus has enough stored energy), the system unlocks the first portion 150k from the second portion 152k to enable the stored energy to move the sensor 138 (and in some embodiments the needle 156) into the skin of the host.

[0568] The telescoping assembly 132k can lock the third portion 392 to the second portion 152k in response to the third portion 392 reaching a sufficiently distal position relative to the second portion 152k. A protrusion 408 can couple with a hole 410 to lock the third portion 392 to the second portion 152k.

[0569] Some embodiments do not include locking protrusion 408 and do not lock the third portion 392 to the second portion 152k in response to the third portion 392 reaching a sufficiently distal position relative to the second portion 152k.

[0570] In several embodiments, sufficiently distal positions are at least 3 millimeters, at least 5 millimeters, and/or less than 30 millimeters distal relative to the proximal starting position.

[0571] The telescoping assembly 132k can lock the first portion 150k to the second portion 152k in response to the first portion 150k reaching a sufficiently distal position relative to the second portion 152k. A protrusion 412 (e.g., a distal protrusion) can couple with a hole 414 (e.g., in a surface that is within plus or minus 30 degrees of perpendicular to the central axis of the telescoping assembly 132k) to lock the first portion 150k to the second portion 152k.

[0572] Some embodiments include a needle 156 to help insert a sensor into skin of a host. In embodiments that include a needle 156, the telescoping assembly 132k can include the

needle retraction mechanism 158 described in the context of Figure 7. Moving the first portion 150k to a sufficiently distal position relative to the second portion 152k can trigger the needle retraction mechanism 158 (e.g., can release a latch) to enable a second spring 234 to retract the needle 156.

[0573] Figure 61 illustrates a system for applying an on-skin sensor assembly 600 (shown in Figures 4-6) to a skin of a host. The system comprises a telescoping assembly 132k having a first portion 150k configured to move distally relative to a second portion 152k from a proximal starting position (e.g., the position shown in Figure 61) to a distal position (e.g., the position shown in Figure 64) along a path; a sensor 138 (shown in Figure 64) coupled to the first portion 150k; and a base 128 comprising adhesive 126 configured to couple the sensor 138 to the skin. The telescoping assembly 132k can further comprise a third portion 392 configured to move distally relative to the second portion 152k.

[0574] In some embodiments, the first portion 150k is located inside of the second portion 152k such that the second portion 152k wraps around the first portion 150k in a cross section taken perpendicularly to the central axis of the telescoping assembly 132k.

[0575] In some embodiments, a first spring 402 is positioned between the third portion 392 and the second portion 152k such that moving the third portion 392 distally relative to the second portion 152k compresses the first spring 402. The first spring 402 can be a metal helical spring and/or a metal conical spring. In several embodiments, the first spring 402 is a feature molded as part of the third portion 392, as part of the second portion 152k, or as part of the first portion 150k. The first spring 402 can be molded plastic.

[0576] The telescoping assembly 132k can be configured such that the first spring 402 is not compressed in the proximal starting position and/or not compressed during storage. In several embodiments, the telescoping assembly 132k can be configured such that the first spring 402 is not compressed more than 15 percent in the proximal starting position and/or during storage (e.g., to avoid detrimental spring relaxation and/or creep of other components such as at least one of the third portion 392, the second portion 152k, and the first portion 150k).

[0577] Some embodiments that include a needle 156 do not include a needle hub 162. In these embodiments, the second spring 234 can be located between the second portion 152k and the first portion 150k such that moving the first portion 150k distally relative to the second portion 152k compresses the second spring 234 to enable the second spring 234 to push the first

portion 150k proximally relative to the second portion 152k to retract the needle 156 (e.g., after sensor insertion).

[0578] In several embodiments, the second spring 234 is compressed while the telescoping assembly 132k is in the proximal starting position. For example, the second spring 234 can be compressed at the factory while the telescoping assembly 132k is being assembled such that when the user receives the telescoping assembly 132k, the second spring 234 is already compressed (e.g., compressed enough to retract the needle 156).

[0579] The second spring 234 can have any of the attributes and features associated with the spring 234 described in the context of other embodiments herein (e.g., in the context of the embodiment of Figure 7).

[0580] In some embodiments, the movement of the sensor module 134 (e.g., an analyte sensor module) and the sensor 138 (e.g., an analyte sensor) relative to the base 128 can be as described in the context of other embodiments (e.g., as shown by the progression illustrated by Figures 7-11).

[0581] In the proximal starting position of the telescoping assembly 132k, the first portion 150k can be locked to the second portion 152k. The system can be configured such that moving the third portion 392 distally relative to the second portion 152k unlocks the first portion 150k from the second portion 152k.

[0582] In several embodiments, a first proximal protrusion 394 having a first hook 396 passes through a first hole 398 in the second portion 152k to lock the first portion 150k to the second portion 152k. The third portion 392 can comprise a first distal protrusion 404. The system can be configured such that moving the third portion 392 distally relative to the second portion 152k engages a ramp 406 to bend the first proximal protrusion 394 to unlock the first portion 150k from the second portion 152k.

[0583] In some embodiments, the sensor 138 is located within the second portion 152k while the base 128 protrudes from the distal end of the system such that the system is configured to couple the sensor 138 to the base 128 by moving the first portion 150k distally relative to the second portion 152k.

[0584] In several embodiments, a sensor module 134 is coupled to a distal portion of the first portion 150k such that moving the first portion 150k to the distal position couples the sensor module 134 to the base 128. This coupling can be as described in the context of other

embodiments herein. The sensor 138 can be coupled to the sensor module 134 while the first portion 150k is located in the proximal starting position.

[0585] The system can be configured such that the third portion 392 moves distally relative to the second portion 152k before the first spring 402 moves the first portion 150k distally relative to the second portion 152k. The system can be configured such that moving the third portion 392 distally relative to the second portion 152k unlocks the first portion 150k from the second portion 150k and locks the third portion 392 to the second portion 152k.

[0586] A first protrusion 408 couples with a hole 410 of at least one of the second portion 152k and the third portion 392 to lock the third portion 392 to the second portion 152k.

[0587] In some embodiments, the system comprises a second protrusion 412 that couples with a hole 414 of at least one of the first portion 150k and the second portion 152k to lock the first portion 150k to the second portion 152k in response to moving the first portion 150k distally relative to the second portion 152k.

[0588] In several embodiments, a first spring 402 is positioned between the third portion 392 and the second portion 152k such that moving the third portion 392 distally relative to the second portion 152k compresses the first spring 402 and unlocks the first portion 150k from the second portion 152k, which enables the compressed first spring 402 to push the first portion 150k distally relative to the second portion 152k, which pushes at least a portion of the sensor 138 out of the distal end of the system and triggers a needle retraction mechanism 158 to enable a second spring 234 to retract a needle 156.

[0589] In yet another aspect, disclosed herein is a dual spring-based sensor insertion device having a pre-connected sensor assembly (i.e. an analyte sensor electrically coupled to at least one electrical contact before sensor deployment). Such a sensor insertion device provides convenient and reliable insertion of a sensor into a user's skin by a needle as well as reliable retraction of a needle after the sensor is inserted, which are features that provide convenience to users as well as predictability and reliability of the insertion mechanism. The reliability and convenience of a dual spring based sensor insertion device having an automatic insertion and automatic retraction provide is a significant advancement in the field of sensor insertion devices. Furthermore, such a device can provide both safety and shelf stability.

[0590] In several embodiments, the insertion device can include a first spring and a second spring. In such embodiments, either or both of the first spring and the second spring can

be integrally formed with portions of a telescoping assembly, such as the first portion and the second portion of a telescoping assembly. In several embodiments, either or both of the first spring and the second spring can be formed separately from and operatively coupled to portions of the telescoping assembly. For example, in some embodiments, the insertion spring can be integrally formed with a portion of the telescoping assembly while the retraction spring is a separate part which is operatively coupled to a portion of the telescoping assembly.

[0591] In some embodiments, rather than being configured to undergo compression during energization, either or both of the first spring and the second spring can be configured to undergo tensioning during energization. In these embodiments, the couplings between the springs and the portions of the telescoping assembly, as well as the couplings between the moving portions of the assembly (for example in the resting state, and during activation, deployment, and retraction) can be adjusted to drive and/or facilitate the desired actions and reactions within the system. For example, in an embodiment employing a tensioned retraction spring to drive the insertion process, the retraction spring can be coupled to or integrally formed with the second portion of the telescoping assembly. In such an embodiment, the retraction spring can be pre-tensioned in the resting state. In other such embodiments, the retraction spring can be untensioned in the resting state, and tensioned during the sensor insertion process.

[0592] In several embodiments, either or both of the first spring and the second spring can be substantially unenergized and/or unstressed when the system is in a resting state. In several embodiments, either or both of the first spring and the second spring can be energized and/or stressed when the system is in a resting state. As used herein, the term "energized" means that enough potential energy is stored in the spring to perform the desired actions and reactions within the system. In some embodiments, the first spring can be partly energized in the resting state, such that the user can supply a lesser amount of force to fully energize the first spring. In some embodiments, the second spring can be partly energized in the resting state, such that the energy stored in the first spring (either in the resting state or after energization by a user) can provide force to energize the second spring. In some embodiments, the energy stored in the first spring can provide sufficient force to energize the second spring to at least retract the needle from the skin. In some embodiments, either or both of the first spring and the second spring can be compressed or tensioned by 50% or more, 60% or more, 70% or more, 80% or more, 90% or more, or 100% in the resting state. In other embodiments, either or both of the first spring and

the second spring can be compressed or tensioned by 50% or less, 40% or less, 30% or less, 20% or less, 15% or less, 10% or less, 5% or less, or 0% in the resting state.

[0593] In embodiments in which both the first spring and the second spring are substantially unenergized in the resting state, they can be stressed by the same amounts, similar amounts, or entirely different amounts. In embodiments in which both the first spring and the second spring are effectively energized in the resting state, they can be stressed by the same amounts, similar amounts, or entirely different amounts. In embodiments in which the second spring is substantially unenergized in the resting state, the first spring can be configured to store enough energy to drive both the desired movement in the system (e.g., the movement of the first portion in a distal direction), as well as the energization of the second spring.

[0594] With reference now to Figures 71-75, another embodiment of a system 104m for applying an on-skin sensor assembly to skin of a host is illustrated. The embodiment illustrated in Figures 71-75 may reduce the potential of incomplete sensor insertion by precluding sensor insertion until sufficient potential energy is stored in the system. The potential energy for inserting the sensor can be stored in an actuator, such as a first spring 402m. The embodiment may provide other advantages such as controlled speed, controlled force, and improved user experience.

[0595] The system 104m may include many features from the embodiment illustrated in Figure 7 (e.g., the needle 156, the base 128 and the sensor module 134). The system 104m may include alternative elements, such as, but not limited to, a needle hub 162m, a second spring 234m, and a needle retraction mechanism 158m. The embodiment illustrated in Figures 71-75 can also be configured to be needle-free by removing the needle 156, the second spring 234m, the needle hub 162m, and the needle retraction mechanism 158m. In such embodiments, the sensor may be a self-insertable sensor.

[0596] The system 104m may include many features that are similar to those of the embodiment illustrated in Figures 61-64 (e.g., a telescoping assembly 132m) including a first portion 150m, a second portion 152m, and a third portion 392m; with locking features 396m and 398m configured to releasably lock the first portion 150m to the second portion 152m until the third portion 392m has reached a sufficiently distal position relative to the second portion 152m to compress the first spring 402m and store enough energy in the spring 402m to drive insertion of the sensor 138 (and in some embodiments the needle 156) into the skin of a host; locking

features 408m and 410m configured to lock the third portion 392m to the second portion 152m (e.g., to prevent proximal movement of the third portion 392m relative to the second portion 152m) in response to the third portion 392m reaching a sufficiently distal position relative to the second portion 152m; unlocking features 404m and 406m configured to unlock the locking features 396m and 398m at least after the third portion 392m is locked to the second portion 152m and/or the first spring 402m is sufficiently compressed; locking features 412m and 414m configured to lock the first portion 150m to the second portion 152m in response to the first portion 150m reaching a sufficiently distal position relative to the second portion 152m to drive the sensor 138 (and in some embodiments the needle 156) into the skin of the host; and a needle retraction mechanism 158m configured to unlock the needle hub 162m from the first portion 150m (e.g., to allow proximal movement of the needle hub 162m with respect to the first portion 150m) at least once the needle hub 162m has reached a sufficiently distal position and thereby enable a second spring 234m to retract the needle 156).

[0597] Figure 71 illustrates a cross-sectional perspective view of the applicator system 104m in a resting state (e.g., as provided to the consumer, before activation by the user and deployment of the applicator system). As illustrated in the figure, the first spring 402m can be neither in tension nor compression, such that the first spring is substantially unenergized. In some embodiments, the first spring 402m can be slightly in tension or slightly in compression (e.g., neither tensioned nor compressed by more than 15 percent) in a resting state, such that the first spring is substantially or mostly unenergized in the resting state. In some embodiments, the first spring can be effectively unenergized, e.g. can be minimally energized but not to an extent that would create any type of chain reaction in the system, in a resting state.

[0598] In the embodiment illustrated in Figures 71-75, the first spring 402m is integrally formed as part of the third portion 392m. In some embodiments, the first spring 402m can be integrally formed as part of other components of the system 104m, such as, but not limited to, the first portion 150m, second portion 152m, etc. An integrally formed spring such as the one illustrated in Figures 71-75 offers advantages including the reduction in the number of parts in a system as well as the reduction in the amount of assembly processes. The first spring 402m can be molded plastic. As illustrated in Figure 71, in the resting state, the second spring 234m is also substantially unenergized (e.g., neither tensioned nor compressed by more than 15 percent). The second spring 234m is integrally formed as part of the needle hub 162m. In some embodiments,

the second spring 234m can be integrally formed as part of other components of the system 104m, such as, but not limited to, the first portion 150m, second portion 152m, base 128, etc. The second spring 234m can be molded plastic. Such a configuration can simplify manufacture and assembly of the system 104m, while avoiding detrimental relaxation and/or creep of the first spring 402m, the second spring 234m, or other components of the system 104m during storage and/or before deployment. It is also contemplated that in other embodiments, the first spring 402m and/or the second spring 234m can comprise metal.

[0599] In some embodiments, first spring 402m and/or second spring 234m can comprise a molded plastic, such as, but not limited to: polycarbonate (PC), acrylonitrile butadiene styrene (ABS), PC/ABS blend, Nylon, polyethylene (PE), polypropylene (PP), and Acetal. In some embodiments, first spring 402m and/or second spring 234m have a spring constant less than 10 lb/inch.

[0600] Applicator system 104 may be energized by moving one component relative to another. For example, moving the third portion 392m distally relative to the second portion 152m, when the second portion 152m is placed against the skin of a host or another surface can store energy in the first spring 402m as it compresses against first portion 150m. The third portion 392m may be moved distally until the locking features 408m and 410m (see Figure 73) engage together. In some embodiments, the third portion 392m may be moved further distally until unlocking features 404m engages locking feature 396m. Unlocking feature 404m may engage and release locking feature 396m and allow first portion 150m to move distally. In some embodiments, locking features 408m and 410m couple together before locking feature 396m is disengaged from locking feature 398m. In other embodiments, unlocking feature 404m engages locking feature 396m and causes locking feature 396m to disengage from locking feature 398m, locking features 408m and 410m may couple together. In some embodiments, locking feature 408m is a protrusion featuring a hook portion, locking feature 410m is a hole featuring an angled surface, unlocking feature 404m is a distal protrusion featuring an angled surface, locking feature 396m is a hook featuring a ramp 406m, and locking feature 398m is an aperture. The sensor module 134 remains in a proximal starting position while the first spring 402m is being energized.

[0601] Figure 72 illustrates a cross-sectional perspective view of the applicator system 104m, with the first spring 402m compressed and with the unlocking features 404m and 406m

engaged so as to unlock the first portion 150m from the second portion 152m. Until the first portion 150m is unlocked from the second portion 152m, the sensor module 134 remains at its proximal starting position, and the second spring 234m remains substantially unenergized. Figure 73 illustrates a rotated cross-sectional perspective view of the applicator system 104m, and shows the locking features 408m and 410m engaged to prevent proximal movement of the third portion 392m with respect to the second portion 152m. In some embodiments, as illustrated in Figure 73, the system can include a secondary locking feature 409m which is configured to cooperate with the opening 410m to prevent the third portion 392 from falling off or otherwise separating from the remainder of the system 104m prior to deployment.

[0602] Figure 74 illustrates a cross-sectional perspective view of the applicator system 104m, with the system 104m having been activated by the disengagement of the first portion 150m with respect to the second portion 152m. As can be seen in Figure 74, once the first portion 150m and the second portion 152m are disengaged or released, the potential energy stored in the first spring 402m drives the first portion 150m in a distal direction along with the needle hub 162m and the sensor module 134. This movement compresses the second spring 234m and deploys the needle 156 and the sensor module 134 distally to a distal insertion position in which the sensor module 134 is coupled to the base 128 and the needle 156 extends distally of the base 128. Once the needle 156 and the sensor module 134 reach the distal insertion position, the locking features 412m, 414m (see Figure 73) engage to prevent proximal movement of the first portion 150m with respect to the second portion 152m, and the unlocking features of the needle retraction mechanism 158m (e.g., the proximal protrusions 170m, the release feature 160m, and the latch 236m comprising ends 164m of the release feature 160m and overhangs 166m of the first portion 150m) cooperate to release the latch 236m. Optionally, the user may hear a click after the second spring 243m is activated, which may indicate to the user that the cap is locked in place.

[0603] Once the latch 236m is released, the potential energy stored in the compressed second spring 234m drives the needle hub 162m back in a proximal direction, while the first portion 150m remains in a distal deployed position along with the sensor module 134. The potential energy stored can be between 0.25 pounds to 4 pounds. In preferred embodiments, the potential energy stored is between about 1 to 2 pounds. Figure 75 illustrates a cross-sectional perspective view of the applicator system 104m with the sensor module 134 in a distal deployed

position, coupled to the base 128, and with the needle hub 162m retracted to a proximal retracted position.

[0604] Systems configured in accordance with embodiments may provide an inherently safe and shelf stable system for insertion of a sensor. An unloaded (i.e. substantially uncompressed and substantially unactivated) spring may not fire prematurely. Indeed, such a system is largely incapable of unintentional firing without direct interaction from a user since the first spring and/or second spring are substantially un-energized on the shelf. Moreover, it is contemplated that a system having a substantially uncompressed spring prior to activation possesses shelf stability since elements of the system are not exposed to a force or phase change over time (such as creep, environment, defects from time dependent load conditions, etc.) as compared to pre-energized insertion devices. Substantially uncompressed first and second springs can provide a system where the substantially unenergized first spring 404m is configured to load energy sufficient to drive a sensor from a proximal position to a distal position and also to transfer energy to the second spring 234m to drive a needle to a fully retracted position.

[0605] Other embodiments can also be configured to achieve these benefits. For example, Figures 76-79 illustrate another embodiment of a system 104n for applying an on-skin sensor assembly to skin of a host. The system 104n includes many features that are similar to those of the embodiment illustrated in Figures 71-75 (e.g., a telescoping assembly 132n including a first portion 150n, a second portion 152n, and a third portion 392n; a needle hub 162n; a first spring 402n; and a second spring 234n). In the embodiment illustrated in Figures 76-79, the first spring 402n is formed separately from and operatively coupled to the third portion 392n. The second spring 234n is formed separately from and operatively coupled to the needle hub 162n. The first spring and/or the second spring can each comprise a helical spring having a circular cross section. In some embodiments, the first spring and/or the second spring can each comprise a helical spring having a square or non-circular cross section. The first spring and/or the second spring can comprise metal, such as, but not limited to, stainless steel, steel, or other types of metals. Alternatively, in some embodiments, one or both of the first spring and the second spring can be integrally formed with a portion of the applicator assembly. For example and without limitation, in some embodiments the first spring can be integrally formed with the first portion. In some embodiments, the second spring can be integrally formed with the needle

hub. In several embodiments, the first spring and/or the second spring can be molded plastic, such as, but not limited to, PC or ABS.

[0606] Figure 76 illustrates a cross-sectional side view of the system 104n in a resting state, in which both the first spring 402n and the second spring 234n are unstressed and unenergized. In the resting state, the first portion 150n can be fixed with respect to the second portion 152n, at least in an axial direction, whereas the third portion 392n is movable in at least a distal direction with respect to the first portion 150n. The first portion 150n and the second portion 152n can be fixed with respect to one another in any suitable fashion, for example by cooperating releasable locking features (e.g., the locking features as described in Figures 71-75, or similar features) coupled to or forming part of the first portion 150n and the second portion 152n. The system 104n includes an on-skin component 134n which is releasably coupled to the needle hub 162n. The on-skin component can comprise a sensor module, such as the sensor module 134 described in connection with Figure 3, or a combined sensor module and base assembly, or an integrated sensor module/base/transmitter assembly, or any other component which is desirably applied to the skin of a host, whether directly or indirectly, for example via an adhesive patch.

[0607] In the resting state illustrated in Figure 76, the on-skin component 134n is disposed at a proximal starting position, between the proximal and distal ends of the system 104n. The distal end of the needle 156 may also be disposed between the proximal and distal ends of the system 104n. In the resting state, the distal end of the first spring 402n abuts a proximally-facing surface of the first portion 150n. The application of force against the proximally-facing surface of the third portion 392n causes the third portion 392n to move distally with respect to the first portion 150n, compressing and thus energizing the first spring 402n. In some embodiments, this process may be similar to the spring energization process described in connection with Figure 71.

[0608] Figure 77 illustrates a cross-sectional side view of the applicator system of Figure 76, with the first spring 402n energized. When the third portion 392n has been moved sufficiently distally to energize the first spring 402n, the third portion 392n becomes fixed, at least in an axial direction, with respect to the second portion 152n. At or about the same time (e.g. simultaneously or subsequently), the first portion 150n becomes movable in at least a distal direction with respect to the second portion 152n. The third portion 392n and the second portion

150n can be fixed with respect to one another in any suitable fashion, for example by cooperating locking features (e.g., the locking features described in Figures 71-75, or similar features) coupled to or forming part of the third portion 392n and the second portion 152n, which are configured to engage with one another once the third portion 392n has reached a sufficiently distal position. The first portion 150n and the second portion 152n can be rendered movable with respect to one another by structure(s) (not shown in Figures 76-79) configured to release the locking features which coupled them together in the resting configuration illustrated in Figure 76. The first portion 150n includes overhangs (sometimes referred to as detents, undercuts, and/or needle hub engagement features) 166n which cooperate with release feature 160n of the needle hub 162n to fix the needle hub 162n with respect to the first portion 150n, both while the system is in a resting state and during energization of the spring 392n.

[0609] Figure 78 illustrates a cross-sectional side view of the system 104n, with the first portion 150n and the second portion 152n unlocked, activating the first spring 402n and allowing the energy stored therein to drive the first portion 150n in a distal direction. The movement of the first portion 150n also urges the needle hub 162n (as well as the on-skin component 134n which is coupled to the needle hub 162n) in a distal direction, compressing the second spring 234n against a proximally-facing surface of the second portion 152n, coupling the on-skin component 134n to the base 128n, and driving the needle 156 into the distal insertion position illustrated in Figure 78. When the needle hub 162n has reached a sufficiently distal position to achieve these functions, the ends of the release feature 160n contact ramps 170n of the second portion 152n which cause the release feature 160n to compress inward (towards the central axis of the system 104n), disengaging the ends of the release feature 160n from the overhangs 166n. In some embodiments, this process may be similar to the spring compression process described in connection with Figure 74. In some embodiments, ramps 170n are proximally facing ramps. In other embodiments, ramps 170n are distally facing ramps (not shown). In some embodiments, the release feature or features can be configured to be compressed inward (or otherwise released) by relative rotational movement of certain components of the system, such as, for example, by twisting or other rotational movement of the first portion with respect to the second portion. In some embodiments, the release feature or features can extend in a direction normal to the axis of the system, and/or can extend circumferentially about the axis of the system, instead of (or in addition to) extending generally parallel to the axis of the system as illustrated in Figure 78.

[0610] Figure 79 illustrates a cross-sectional side view of the system 104n, with the needle hub 162n released from engagement with the overhangs 166, activating the second spring 234n and allowing the energy stored therein to drive the needle hub 162n in a proximal direction. As the needle hub 162n retracts to a proximal position, the on-skin component 134n decouples from the needle hub 162n to remain in a deployed position, coupled to the base 128n.

[0611] Figures 80-85 illustrate another embodiment of a system 104p for applying an on-skin sensor assembly to skin of a host. A sensor insertion system such as the one illustrated in Figures 80-85 may provide enhanced predictability in spring displacement of the second energized spring 234p because the second spring 234p is already compressed. Such a configuration can aid in properly ensuring the needle is retracted at a sufficient distance from the skin. In some embodiments, a system incorporating a pre-energized retraction spring can provide effective and reliable insertion and retraction while requiring a lesser amount of user-supplied force than, for example, a system in which both the insertion and retraction springs are substantially unenergized prior to deployment, making such a configuration more convenient for at least some users. Further, in some embodiments, a system incorporating one or more metal springs can provide effective and reliable insertion and retraction while requiring a lesser amount of force than a system in which both the insertion and retraction springs comprise plastic. The system 104p includes many features that are similar to those of the embodiment illustrated in Figures 76-79 (e.g., a telescoping assembly 132p including a first portion 150p, a second portion 152p, and a third portion 392p; a needle hub 162p; a first spring 402p; a second spring 234p; an on-skin component 134n, and a base 128p). In the embodiment illustrated in Figures 80-85, the first spring 402p is formed separately from and operatively coupled to the third portion 392p. The second spring 234p is formed separately from and operatively coupled to the needle hub 162p. The first spring and/or the second spring can comprise metal. Alternatively, in some embodiments, one or both of the first spring and the second spring can be integrally formed with a portion of the applicator assembly. For example and without limitation, in some embodiments the first spring can be integrally formed with the first portion. In some embodiments, the second spring can be integrally formed with the needle hub. In several embodiments, the first spring and/or the second spring can be molded plastic.

[0612] Figure 80 illustrates a cross-sectional side view of the system 104p in a resting state, in which the first spring 402p is substantially unstressed and unenergized, but in which the

second spring 234n is pre-energized (e.g., compressed). In the resting state illustrated in Figure 80, the first portion 150p is locked to the second portion 152p so as to prevent proximal or distal movement of the first portion 150p with respect to the second portion 152p. The first portion 150p and the second portion 152n can be locked together in any suitable fashion, for example by cooperating releasable locking features 396p and 398p (see Figures 84 and 85) coupled to or forming part of the first portion 150p and the second portion 152p. The needle hub 162n is also releasably fixed to the first portion 150p. The needle hub 162n can be fixed to the first portion 150p in any suitable fashion, for example by features of the first portion 150p configured to engage or compress release feature (sometimes referred to as needle hub resistance features) 160p of the needle hub 162p.

[0613] In the resting state illustrated in Figure 80, the on-skin component 134p is disposed at a proximal starting position, such that the distal end of the needle 156 is disposed between the proximal and distal ends of the system 104p. In the resting state, the distal end of the first spring 402p abuts a proximally-facing surface of the first portion 150p. The application of force against the proximally-facing surface of the third portion 392p causes the third portion 392p to move distally with respect to the first portion 150p, compressing and thus energizing the first spring 402p. In some embodiments, this process may be similar to the spring energization process described in connection with Figure 76.

[0614] Figure 81 illustrates a cross-sectional side view of the system 104p of Figure 80, after the third portion 392n has been moved to a sufficiently distally position to energize the first spring 402p and optionally lock the third portion 392p to the second portion 152p. The third portion 392n and the second portion 150n can lock together in any suitable fashion, for example by cooperating locking features (e.g., the locking features described in Figures 76-79, or similar features) coupled to or forming part of the third portion 392p and the second portion 152p. At or about the same time as the third portion 392p locks to the second portion 152p (e.g. simultaneously or subsequently), the unlocking features 404p and 406p (see Figures 84 and 85) cooperate to release the lock between the first portion 150p and the second portion 152p.

[0615] Figure 82 illustrates a cross-sectional side view of the system 104p, with the first spring 402p activated to drive the first portion 150p in a distal direction. The movement of the first portion 150p also urges the needle hub 162p (as well as the on-skin component 134p which is coupled to the needle hub 162p) in a distal direction, coupling the on-skin component 134p to

the base 128p, and also driving the needle 156 in a distal direction, past a distal end of the system 104p. At or about the time the needle hub 162p reaches the distal insertion position illustrated in Figure 82 (e.g., immediately before, simultaneously, or subsequently), the ends of the release feature 160p contact ramps 170p of the second portion 152p, causing the release feature 160p to compress inward (towards the central axis of the system 104p), unlocking the needle hub 162p from the first portion 150p and releasing or activating the second spring 234p. In some embodiments, ramps 170p are proximally facing ramps. In other embodiments, ramps 170p are distally facing ramps (not shown). Activation of the second spring 234p urges the needle hub 162p in a proximal direction.

[0616] Figure 83 illustrates a cross-sectional side view of the system 104p, with the needle hub 162p unlocked from the first portion 150p and retracted to a proximal position. As the needle hub 162p retracts to a proximal position, the on-skin component 134p decouples from the needle hub 162p to remain in a deployed position, coupled to the base 128p.

[0617] Figure 84 illustrates a perspective view of the system 104p in a resting state, with the first portion 150p and the third portion 392p shown in cross section to better illustrate certain portions of the system 104p, such as the locking features 396p, 398p and the unlocking features 404p, 406p. Figure 85 illustrates another perspective view of the system 104p, also with the first portion 150p and the third portion 392p shown in cross section, with the first spring 402p energized but not yet activated.

[0618] Figures 86-88 illustrate another embodiment of a system 104q for applying an on-skin sensor assembly to skin of a host, wherein the insertion spring is pre-compressed and the retraction spring is substantially uncompressed. Such a system may allow a user to activate the insertion and retraction of a needle with fewer steps. It is contemplated that advantages may include a relatively smaller applicator size and more predictable spring displacement of the first spring because the first spring is already compressed, thereby aiding in ensuring proper needle insertion into the skin of a user. In some embodiments, a system incorporating a pre-energized insertion spring can provide effective and reliable insertion and retraction while requiring a lesser amount of user-supplied force than, for example, a system in which both the insertion and retraction springs are substantially unenergized prior to deployment, making such a configuration more convenient for at least some users. The system 104q includes many items that are similar to those of the embodiment illustrated in Figures 76-79 (e.g., a telescoping assembly 132q

including a first portion 150q, a second portion 152q, and a third portion 392q; a needle hub 162q; a first spring 402q; a second spring 234q; an on-skin component 134q, and a base 128q). In the system 104q, the first spring 402q is formed separately from and operatively coupled to the third portion 392q. The second spring 234q is formed separately from and operatively coupled to the needle hub 162q. The first spring and/or the second spring can comprise metal. Alternatively, in some embodiments, one or both of the first spring and the second spring can be integrally formed with a portion of the applicator assembly.

[0619] Figure 86 illustrates a cross-sectional side view of the system 104q in a resting state, in which the first spring 402q is already energized but in which the second spring 234q is substantially unenergized (e.g. mostly uncompressed or unstressed; can be partially energized). In the resting state illustrated in Figure 86, the first portion 150q is locked to the second portion 152q so as to prevent proximal or distal movement of the first portion 150q with respect to the second portion 152q. The first portion 150q and the second portion 152q can be locked together in any suitable fashion, for example by cooperating releasable locking features (e.g., the locking features described in Figures 76-79 or other suitable locking features) coupled to or forming part of the first portion 150q and the second portion 152q. The needle hub 162q is also releasably locked to the first portion 150q. The needle hub 162q can be locked to the first portion 150q in any suitable fashion, for example by features of the first portion 150q configured to engage or compress release feature 160q of the needle hub 162q. The third portion 392q and the second portion 152q are also locked together, so as to prevent relative movement of the third portion 392p and the second portion 152q in the axial direction. The third portion 392q and the second portion 152q can be locked together in any suitable fashion, for example by cooperating locking features (not shown in Figures 86-89), which may be coupled to or form part of the third portion 392q and the second portion 152q. In the resting state illustrated in Figure 80, the on-skin component 134q is disposed at a proximal starting position, such that the distal end of the needle 156 is disposed between the proximal and distal ends of the system 104q.

[0620] To trigger deployment of the system 104q, the locking features coupling the first portion 150q to the second portion 152q can be unlocked, decoupling these two portions and thereby releasing or activating the first spring 402q. The locking features can be unlocked by a user-activated trigger mechanism, such as, for example, a button disposed on or in a top or side surface of the system 104q, or a twist-release feature configured to disengage the locking

features when the third portion 392q is rotated about the axis of the system, relative to the first portion 150q and/or the second portion 152q. Some examples of triggering mechanisms are described in connection with Figures 92-104.

[0621] Figure 87 illustrates a cross-sectional side view of the system 104q, after the first portion 150q and the second portion 152q have been unlocked. As can be seen in Figure 87, the first spring 402q drives the first portion 150q in a distal direction as the first spring 402q expands. The movement of the first portion 150q also urges the needle hub 162q (as well as the on-skin component 134q which is coupled to the needle hub 162q) in a distal direction, coupling the on-skin component 134q to the base 128q, compressing the second spring 234q, and driving the needle 156 in a distal direction past a distal end of the system 104q. At or about the time the needle hub 162q reaches the distal insertion position illustrated in Figure 87 (e.g., immediately before, simultaneously, or subsequently), the ends of the release feature 160q contact interference features 170q of the second portion 152q, causing the release feature 160q to compress inward (towards the central axis of the system 104q), unlocking the needle hub 162q from the first portion 150q and activating the now-energized second spring 234q. In some embodiments, interference features 170q are proximally facing interference features. In other embodiments, interference features 170q are distally facing interference features (not shown).

[0622] Activation of the second spring 234q by the user or mechanisms urges the needle hub 162q in a proximal direction, while the on-skin component 134q, having been coupled to the base 128q, remains in a deployed distal position. Figure 88 illustrates a cross-sectional side view of the system 104q, with the on-skin component 134q in a deployed position and the needle hub 162q retracted to a proximal position.

[0623] Figures 89-91 illustrate another embodiment of a system 104r for applying an on-skin sensor assembly to skin of a host. It is contemplated that the system 104r as illustrated with reference to Figures 89-91 provides for predictable spring displacement of the first spring 402r because it is compressed, thereby aiding in proper needle insertion into the skin of the user. Moreover, it is contemplated that the compressed second spring 234r provides predictable spring displacement and aids in properly ensuring that the needle is properly retracted from the skin of the user. In some embodiments, a system incorporating pre-energized insertion and retraction springs can provide effective and reliable insertion and retraction while requiring a lesser amount of user-supplied force than, for example, a system in which one or both of the insertion and

retraction springs are substantially unenergized prior to deployment, making such a configuration more convenient for at least some users. The system 104r includes many items that are similar to those of the embodiment illustrated in Figures 76-79 (e.g., a telescoping assembly 132r including a first portion 150r, a second portion 152r, and a third portion 392r; a needle hub 162r; a first spring 402r; a second spring 234r; an on-skin component 134r, and a base 128r). As illustrated in Figures 89-91, both the first spring 402r and the second spring 234r are pre-compressed. In the system 104r, the first spring 402r is formed separately from and operatively coupled to the third portion 392r. The second spring 234r is formed separately from and operatively coupled to the needle hub 162r. The first spring and/or the second spring can comprise metal. Alternatively, in some embodiments, one or both of the first spring and the second spring can be integrally formed with a portion of the applicator assembly.

[0624] Figure 89 illustrates a cross-sectional side view of the system 104r in a resting state, in which both the first spring 402r and the second spring 234r are pre-energized (e.g., compressed sufficiently to drive the needle insertion and retraction processes). In the resting state illustrated in Figure 89, the first portion 150r is locked to the second portion 152r so as to prevent proximal or distal movement of the first portion 150r with respect to the second portion 152r. The first portion 150r and the second portion 152r can be locked together in any suitable fashion, for example by cooperating releasable locking features (e.g., the locking features described in connection with Figures 80-83, or other suitable locking features) coupled to or forming part of the first portion 150r and the second portion 152r. The needle hub 162r is also releasably locked to the first portion 150r. The needle hub 162r can be locked to the first portion 150r in any suitable fashion, for example by features of the first portion 150r configured to engage or compress release feature 160r of the needle hub 162r. The third portion 392r and the second portion 152r are also locked together, so as to prevent relative movement of the third portion 392p and the second portion 152r in at least the axial direction. The third portion 392r and the second portion 152r can be locked together in any suitable fashion, for example by cooperating locking features (not shown in Figures 89-91), which may be coupled to or form part of the third portion 392r and the second portion 152r. In the resting state illustrated in Figure 89, the on-skin component 134r is disposed at a proximal starting position, such that the distal end of the needle 156 is disposed between the proximal and distal ends of the system 104r.

[0625] To trigger deployment of the system 104r, the locking features coupling the first portion 150r to the second portion 152r can be unlocked, decoupling these two portions and thereby releasing or activating the first spring 402r. Figure 90 illustrates a cross-sectional side view of the system 104r, after the first portion 150r and the second portion 152r have been unlocked. As can be seen in Figure 90, the first spring 402r drives the first portion 150r in a distal direction as the first spring 402r expands or decompresses. The movement of the first portion 150r also urges the needle hub 162r (as well as the on-skin component 134r which is coupled to the needle hub 162r) in a distal direction until the on-skin component 134r is coupled to the base 128r, and until the needle 156 reaches a distal insertion position beyond a distal end of the system 104r. At or about the time the needle hub 162r reaches the distal insertion position illustrated in Figure 87 (e.g., immediately before, simultaneously, or subsequently), the ends of the release feature 160r contact corresponding interference features 170r of the second portion 152r, causing the release feature 160r to compress inward (towards the central axis of the system 104r), unlocking the needle hub 162r from the first portion 150r and releasing or activating the second spring 234r.

[0626] Activation of the second spring 234r drives the needle hub 162r in a proximal direction, while the on-skin component 134r, having been coupled to the base 128r, remains in a deployed distal position. Figure 91 illustrates a cross-sectional side view of the system 104r, with the on-skin component 134r in a deployed position and the needle hub 162r retracted to a proximal position. From this configuration, the system 104r can be removed and separated from the deployed on-skin component 134r and the base 128r.

[0627] Figures 92-100 illustrate yet another embodiment of a system 104s for applying an on-skin sensor assembly to skin of a host comprising a safety feature to prevent accidental firing of the sensor insertion device. The system 104s includes many items that are similar to those of the embodiment illustrated in Figures 76-79 (e.g., a telescoping assembly 132s including a first portion 150s, a second portion 152s, and a third portion 392s; a needle hub 162s; a first spring 402s; a second spring 234s; an on-skin component 134s, and a base 128s). In the system 104s, the first spring 402s may be formed separately from and operatively coupled to the third portion 392s. The second spring 234s may be formed separately from and operatively coupled to the needle hub 162s. The first spring and/or the second spring can comprise metal. Alternatively,

in some embodiments, either or both of the first spring and the second spring can be integrally formed with a portion of the applicator assembly.

[0628] Figure 92 illustrates a side view of the system 104s in a resting state, in which the first spring 402s is unstressed and unenergized, but in which the second spring 234s is already energized (e.g., compressed). The system 104s includes a cocking mechanism 702 by which the first spring 402s can be energized (e.g. compressed) without automatically triggering deployment of the first portion 150s or activation of the first spring 402s. The system 104s also includes a trigger button 720 configured to activate the first spring 402s after the system is cocked. Figure 93 illustrates a side view of the applicator system 104s, after being cocked but before being triggered.

[0629] Figure 94 illustrates a cross-sectional perspective view of the system 104s in a resting state, showing the first spring 402s substantially uncompressed. The cocking mechanism 702 includes a pair of proximally-extending lever arms 704, each with a radially-extending angled tab 706. In some embodiments, the lever arms 704 can be integrally formed with the second portion 152s, as shown in Figure 94, while in other embodiments, the lever arms 704 can be separate from and operatively coupled to the second portion 152s. In the resting state illustrated in Figure 94, the angled tabs 706 extend through distal apertures 708 in the third portion 392s so as to prevent proximal movement of the third portion 392s with respect to the second portion 152s. The angled tabs 706 are also configured to inhibit distal movement of the third portion 392s with respect to the second portion 152s, unless and until a sufficient amount of force is applied to the third portion 392s to deflect the angled tabs 706 and the lever arms 704 inward, as illustrated in Figure 95.

[0630] As sufficient force is applied to the third portion 392s in a distal direction (e.g. by the hand or thumb of a user), the angled tabs 706 deflect inward and release from engagement with the distal apertures 708, allowing the third portion 392s to move distally with respect to the second portion 152s. This may allow the user to compress and energize the first spring 402s. When the third portion 392s has reached a sufficiently distal position to compress the first spring 402s enough to drive the sensor into the skin of a host, the angled tabs 706 engage with proximal apertures 710 of the third portion 392s to lock the position of the third portion 392s with respect to the second portion 152s, as illustrated in Figure 96. The angled tabs 706 may be configured to generate a "click" sound when engaged to proximal apertures 710 so as to prevent proximal

movement of the third portion 392s with respect to the second portion 152s, so that a user can feel and/or hear when these parts are engaged. In the configuration illustrated in Figure 96, the system 104s is energized in which the third portion 392 is in a cocked position. The system 104s is ready to deploy the sensor, but does not deploy until further action is taken by the user.

[0631] Figure 97 illustrates a cross-sectional side view of the system 104s, in a cocked but untriggered state. In this state, the first portion 150s is locked to the second portion 152s so as to prevent proximal or distal movement of the first portion 150s with respect to the second portion 152s. The first portion 150s and the second portion 152s can be locked together in any suitable fashion, for example by cooperating releasable locking features 396s and 398s operatively coupled to or forming part of the first portion 150s and the second portion 152s. The trigger button 720 includes a distally-extending protrusion 722 which, once depressed to a sufficiently distal position by a user, is configured to cooperate with an unlocking feature 406s of the locking feature 396s to decouple the first portion 150s from the second portion 152s. The trigger button 720 can be operatively coupled to the third portion 392s, as illustrated in Figures 92-100, or can be integrally formed with the third portion, for example as a lever arm formed within a proximal or side surface of the third portion. In some embodiments, the trigger button can be disposed at the top of the system (such that the application of force in the distal direction triggers the system to activate), or at a side of the system (such that the application of force in a radially inward direction, normal to the direction of needle deployment, triggers system to activate).

[0632] Figure 98 illustrates a cross-sectional side view of the energized system 104s as the trigger button 720 has been depressed sufficiently to cause the protrusion 722 to flex the locking feature 396s radially inward, disengaging it from the opening 398s and unlocking the first portion 150s from the second portion 152s. Depressing the trigger button 720 thus activates the first spring 402, pushing the first portion 150s and the needle hub 162s, along with the on-skin component 134s which is coupled thereto, in a distal direction until the on-skin component is coupled to the base 128s, as illustrated in Figure 99. At or about the time the needle hub 162s reaches the distal insertion position illustrated in Figure 99 (e.g., immediately before, simultaneously, or subsequently), corresponding release features of the needle hub 162s and the first portion 150s can engage (via, for example, the release features described in any of Figures 76-91, or any other suitable release features), releasing the needle hub 162s from the first portion

150s and releasing or activating the second spring 234s. Activation of the second spring 234s urges the needle hub 162s in a proximal direction.

[0633] Figure 100 illustrates a cross-sectional side view of the applicator system of Figure 92, with the on-skin component 134s in a deployed position and the needle hub 162s retracted to a proximal position. As the needle hub 162s retracts to a proximal position, the on-skin component 134s decouples from the needle hub 162s to remain in a deployed position, coupled to the base 128s. From this configuration, the remainder of the system 104s can be removed and separated from the deployed on-skin component 134s and the base 128s.

[0634] Any of the features described in the context of any of Figures 61-99 can be applicable to all aspects and embodiments identified herein. For example, the embodiments described in the context of Figures 61-64 can be combined with the embodiments described in the context of Figures 1-60 and 65-70. As another example, any of the embodiments described in the context of Figures 92-109 can be combined with any of the embodiments described in the context of Figures 1-60 and 65-91 and 110-143. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

TRIGGER MECHANISMS AND SAFETY LOCKS

[0635] In some embodiments, the application of enough force to sufficiently energize the first spring to drive insertion of the sensor can also serve to activate the first spring. In other embodiments, the energizing of the first spring can be decoupled from the activation of the first spring, requiring separate actions on the part of the user to energize (e.g. compress) the first spring and to trigger deployment of the system.

[0636] For example, the embodiment illustrated in Figures 92-100 includes a trigger mechanism in the context of a user-energized actuator. In such an embodiment, the user first cocks the system 104s to energize the first spring 402s, and then, in a separate action, triggers the activation of the first spring 402s using the trigger button 720. The locking feature is easy to release by the user and when combined with a trigger mechanism, allows for single handed use.

[0637] In some embodiments, the actuator or insertion spring is already energized when the system is in a resting state. In these embodiments, a trigger mechanism, such as the trigger mechanism described in the context of Figures 92-100, can be used to activate the already-energized insertion spring without any action by the user to energize the spring.

[0638] Figure 101 illustrates a side view of one such applicator system 104t, with a side trigger button 730. The system 104t can be configured substantially similar to the system 104q or the system 104r illustrated within the context of Figures 86-88 and 89-91, respectively, with like reference numerals indicating like parts. As can be seen in Figure 101, the trigger button 730 is operatively coupled to the third member 392t.

[0639] Figure 102 illustrates another side view of the system 104t, with the first portion 150t and the third portion 392t shown in cross-section to illustrate the trigger mechanism. As can be seen in Figure 102, the trigger button 730 includes a protrusion 732 that extends radially inward, toward a central axis of the system 104t. The protrusion 732 is radially aligned with the locking feature 396t of the first portion 150t. When a user exerts a sideways (e.g., radially inward) force on the trigger button 730, the protrusion 732 urges the locking feature 396t radially inward, releasing it from engagement with the ledge feature 398t (which may be configured similarly to, for example, the ledge locking feature 398p illustrated in Figures 84 and 85) in the second portion 152t and activating the first spring 402t. In other embodiments, the locking features 396, 398 can comprise cooperating structure of a key/keyway mechanism which is configured to release when the features 396, 398 are brought into a certain orientation with respect to one another (e.g., using a radially applied force, an axially applied force, a twisting movement or rotational force, or other type of activation).

[0640] Figure 103 illustrates a side view of another applicator system 104u, with an integrated side trigger button 730. The system 104u can be configured substantially similar to the system 104q or the system 104r illustrated within the context of Figures 86-88 and 89-91, respectively, with like reference numerals indicating like parts. As can be seen in Figure 103, the trigger button 740 is a distally-extending lever arm integrally formed in the third member 392u. Figure 104 illustrates another side view of the system 104u, with the first portion 150u and the third portion 392u shown in cross-section to better illustrate the trigger mechanism. As can be seen in Figure 104, the trigger button 740 is radially aligned with a radially-extending tab 742 of the first portion 150u. The tab 742 is connected to the locking feature 396u via an elongated

member 394u, which acts as a lever arm. In some embodiments, tab 742 locking feature 396u, and elongated member 394u are integrally formed together. When a user exerts a sideways (e.g., radially inward) force on the trigger button 740, the button 740 pushes the tab 742 radially inward, releasing the locking feature 396u from engagement with the locking feature 398u in the second portion 152u and activating the first spring 402u.

[0641] Trigger mechanisms such as those described in the context of any of Figures 92-104 can be used in embodiments comprising pre-energized actuators or insertion springs, as well as in embodiments comprising user-energized actuators or insertion springs.

[0642] In several embodiments, a sensor inserter system can include a safety mechanism configured to prevent premature energizing and/or actuation of the insertion spring. Figures 105-109 illustrate one such system 104v, which incorporates a safety lock mechanism 750. Figure 105 illustrates a perspective view of the system 104v. The system 104v can be configured substantially similar to any of the systems 104m, 104n, 104p illustrated within the context of Figures 71-87, with like reference numerals indicating like parts. The safety lock mechanism 750 includes a release button 760, which can be integrally formed with the third portion 392v as shown in Figure 105 (similar to the trigger button 740 described in connection with Figures 103-104), or which can be operatively coupled to the third portion 392v. In the system 104v, the release button 760 comprises a lever arm which is integrally formed in a side of the third portion 392v, although other configurations (e.g. a top button) are also contemplated. The release button can be configured to protrude radially from a side or a top of the third portion, or can be configured with an outer surface which is flush with the surrounding surface of the third portion 392v.

[0643] Figure 106 illustrates a cross-sectional perspective view of a portion of the system 104v, with the safety mechanism 750 in a locked configuration and the first spring 402v unenergized. The safety mechanism 750 includes a proximally-extending locking tab 752 of the second portion and an inwardly-extending overhang (or undercut) 754 of the third portion 392v. In the locked configuration illustrated in Figure 106, the tab 752 is flexed radially outward and its proximal end is constrained by the overhang 754, preventing distal movement of the third portion 392v with respect to the second portion 152v and thus preventing energization of the spring 392v. The release button 760 includes a protrusion 758 which extends inwardly, in radial alignment with a portion of the tab 752. A lateral (e.g. radially inward) force applied to the

release button 760 pushes the tab 752 radially inward, sliding the proximal end of the tab 752 against an angled surface 756 of the overhang 754 and out of engagement with the overhang 754, so that the tab 752 can release to an unstressed configuration as shown in Figure 108. Once the tab 752 is released, the third portion 392v can be moved distally with respect to the second portion 152v, for example to energize the first spring 402v. In some embodiments, as illustrated in Figure 109, the tab 752 can be configured to prevent further distal movement of the third portion 392v beyond a desired threshold, for example by abutting a distally-facing surface 762 of the third portion 392v.

[0644] Although the safety lock mechanism 750 is illustrated in the context of a system configured to be energized by a user, in some embodiments, a pre-energized system can also employ a safety lock mechanism, for example to prevent premature triggering or activation of an already energized spring.

[0645] In some embodiments, the locking and unlocking (and/or coupling and decoupling) of the components of a sensor inserter assembly can follow this order: The sensor inserter assembly begins in a resting state in which the third portion 392 is locked with respect to the first portion 150, the first portion 150 is locked with respect to the second portion 152, and the sensor module 134 is coupled to the first portion 150 (optionally via the needle hub 162). Before energizing or triggering of the insertion spring 402, the third portion 392 is unlocked with respect to the first portion 150 and/or the second portion 150. The insertion spring 402, if not already energized, is then energized by distal movement of the third portion 392. Then, the third portion 392 is locked with respect to the second portion 152. The first portion 150 is then released from the second portion 152 to activate the insertion spring 402. As the insertion spring 402 deploys, the sensor module 134 couples to the base 128. Then the first portion 150 (and/or the needle hub 162) releases the sensor module 134, and the second portion 152 releases the base 128. In several embodiments, the locations of the various locking and unlocking (and/or coupling and decoupling) structures along the axis of the assembly are optimized to ensure this order is the only order that is possible. (Some embodiments use different locking and unlocking orders of operation.)

[0646] Systems such as those illustrated in Figures 92-109 provide reliable trigger mechanisms to release an insertion spring when the insertion spring is in a loaded condition. It is contemplated such systems provide several advantages to the user including ease in firing, single

handed firing (by allowing the user to hold onto the sides of the insertion device and fire the insertion device using the same hand). It is contemplated that a system comprising a top trigger can provide a smaller width profile than a system having a side button while requiring less user dexterity.

RELEASE AFTER DEPLOYMENT

[0647] In several embodiments, a sensor inserter system is configured to move an on-skin component (such as, for example, a sensor module 134, a sensor assembly (for example comprising a sensor, electrical contacts, and optionally a sealing structure), a combination sensor module and base, an integrated sensor module and transmitter, an integrated sensor module and transmitter and base, or any other component or combination of components which is desirably attached to the skin of a host) from a proximal starting position within the sensor inserter system to a distal deployed position in which it can attach to the skin of a host, while at the same time inserting a sensor (which may form part of the on-skin component) into the skin of the host. In some embodiments, the sensor is coupled to electrical contacts of the on-skin component during the deployment and/or insertion process. In other embodiments, the on-skin component is pre-connected, that is to say, the sensor is coupled to electrical contacts of the on-skin component before the deployment and/or insertion processes begin. The sensor assembly can be pre-connected, for example, during manufacture or assembly of the system.

[0648] Thus, in several embodiments, a sensor inserter system can be configured to releasably secure the on-skin component in its proximal starting position, at least before or until deployment of the inserter system, and can also be configured to release the on-skin component in a distal position after the inserter system is deployed. In some embodiments, the system can be configured to couple the on-skin component to a base and/or to an adhesive patch during the deployment process, either as the on-skin component is moved from the proximal starting position to the distal deployed position or once it reaches the distal deployed position. In some embodiments, the system can be configured to separate from (or become separable from) the on-skin component, base, and/or adhesive patch after the on-skin component is deployed in the distal position and the needle hub (if any) is retracted.

[0649] In embodiments, various mechanical interlocks (e.g., snap fits, friction fits, interference features, elastomeric grips) and/or adhesives can be used to couple the on-skin component to the sensor inserter system and releasably secure it in a proximal starting position,

and/or to couple the on-skin component (and base, if any) to the adhesive patch once the on-skin component is deployed. In addition, various mechanical features (e.g. snap fits, friction fits, interference features, elastomeric grips, pushers, stripper plates, frangible members) and/or adhesives can be used to decouple the on-skin component from the sensor inserter system once it reaches the distal deployed position. Further, various mechanical features, (e.g. snap fits, friction fits, interference features, elastomeric grips, pushers, stripper plates, frangible members) and/or adhesives can be used to separate, unlock, or otherwise render separable the on-skin component, base, and/or adhesive patch from the remainder of the system after the on-skin component is deployed in the distal position and the needle hub (if any) is retracted.

[0650] With reference now to Figures 110-119, a sensor inserter system 104w according to some embodiments is illustrated. The system 104w can be configured substantially similar to the system 104v illustrated within the context of Figures 105-109 and system 104m illustrated within the context of Figures 71-75, with like reference numerals indicating like parts. The system 104w includes, for example, a telescoping assembly 132w including a first portion 150w, a second portion 152w, and a third portion 392w; a safety mechanism 750, a needle hub 162w; a first spring 402w; a second spring 234w; an on-skin component 134w, and a base 128w.

[0651] Figure 110 illustrates a cross-sectional perspective view of the system 104w in a resting and locked state, with the on-skin component 134w secured in a proximal starting position. In this state, as well as in the unlocked state illustrated in Figure 111 and the energized state illustrated in Figure 112, the on-skin component 134w is secured in the proximal starting position by a securement member 800. As can be seen in Figure 110, the system 104w includes a secondary locking feature 409w, configured as a ledge extending from the distal end of the locking protrusion 408w, which is configured to cooperate with an opening 410w to prevent the third portion 392 from moving in a proximal direction with respect to the second portion 152w prior to deployment. In the embodiment illustrated in Figures 110-119, the securement member 800 is integrally formed with the needle hub 162w. In other embodiments, the securement member can be integrally formed with the first portion 150w. In still other embodiments, the securement member can be separately formed from and operatively coupled to the needle hub 162w and/or to the first portion 150w. The securement member 800 extends substantially parallel to the needle 158. In the embodiment illustrated in Figures 110-119, the securement member 800 comprises a pair of distally-extending legs 802 (see Figures 115 and 116). Some embodiments

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can, however, include only one distally-extending leg 802, while others can include three, four, or more legs 802. In embodiments comprising only one leg 802, the leg can be configured to adhere or otherwise couple to a center region or a perimeter of the on-skin component. In embodiments comprising more than one leg 802, the legs can be configured to adhere or otherwise couple to the on-skin component symmetrically or asymmetrically about a center of the on-skin component. The legs 802 can have an ovoid cross section, or can have any other suitable cross section, including circular, square, triangular, curvilinear, L-shaped, O-shaped, U-shaped, V-shaped, X-shaped, or any other regular or irregular shape or combination of shapes. In embodiments, the securement member 800 can comprise legs, columns, protrusions, and/or elongate members, or can have any other suitable configuration for holding the on-skin component in the proximal starting position.

[0652] Figure 113 illustrates a cross-sectional perspective view of the system 104w, in an activated state, with the insertion spring 402w activated, the retraction spring 234w energized, and the needle hub 162w and the securement member 800 moved to a distal deployed position. The on-skin component 134w, being coupled to the securement member 800 until this stage, has also been moved to a distal deployed position. When the on-skin component 134w reaches the distal deployed position, it is coupled to the base 128w.

[0653] Figure 114 illustrates a cross-sectional perspective view of the system 104w after the on-skin component has been coupled to the base 128w and the needle hub 162w (along with the securement member 800) has been retracted to a proximal position. After the on-skin component 134w is coupled to the base 128w, a resistance member 804 facilitates decoupling of the on-skin component 134w from the securement member 800 by resisting unwanted proximal movement of the on-skin component 134w away from the base 128w. Generally, the resistance member 804 can be a backstop or backing structure configured to inhibit or prevent, or otherwise resist any tendency of the on-skin component 134w to move in a proximal direction as the securement member 800, which is releasably coupled to the on-skin component 134w, moves in a proximal direction. Because the first portion 150w is fixed to the second portion 152w at this stage, and the needle hub 162w is released from the first portion 150w, the needle hub 162w can retract in a proximal direction while the first portion 150w (and the resistance member 804) remains planted in a distal position, inhibiting proximal movement of the on-skin component 134w. The energy stored in the retraction spring 234w is sufficient to overcome a retention force

and decouple the on-skin component 134w from the securement member 800 and urge the needle hub 162 in a proximal direction. The potential energy stored can be between 0.25 pounds to 4 pounds. In preferred embodiments, the potential energy stored is between about 1 to 2 pounds.

[0654] In some embodiments, a sensor inserter system can be configured such that the on-skin component couples with the base at approximately the same time the retraction mechanism is activated. In some embodiments, a sensor inserter system can be configured such that the on-skin component couples with the base before the retraction mechanism is activated, before the second spring is activated, or otherwise before the second spring begins retracting the needle hub in a proximal direction away from the deployed position. In some embodiments, a sensor inserter system can be configured such that the second spring is activated at least 0.05 seconds, at least 0.1 seconds, at least 0.2 seconds, at least 0.3 seconds, at least 0.4 seconds, at least 0.5 seconds, at least 0.6 seconds, at least 0.7 seconds, at least 0.8 seconds, at least 0.8 seconds, at least 1 second, or longer than 1 second after the on-skin component couples with the base. In other embodiments, a sensor inserter system can be configured such that the second spring is activated at most 0.05 seconds, at most 0.1 seconds, at most 0.2 seconds, at most 0.3 seconds, at most 0.4 seconds, at most 0.5 seconds, at most 0.6 seconds, at most 0.7 seconds, at most 0.8 seconds, at most 0.8 seconds, or at most 1 second after the on-skin component couples with the base.

[0655] The on-skin component 134w is now coupled with the base 128w. The base 128w (and adhesive patch) is initially coupled to the second portion 152w by a latch or flex arm 220w coupled to an undercut or locking feature 230w (similarly shown in FIGS. 18-19). When the first portion 150w reaches its most distal position during insertion of the sensor 138, a delatching feature of the first portion 150w pushes the latch of the second portion 152w out of the undercut. This decouples the base 128w from the second portion 152w, and thus allows the user to take the remainder of the system 104w off the skin, leaving only the adhesive patch, the base 128w, and the on-skin component 134w on the skin.

[0656] In the embodiment illustrated in Figures 110-119, the resistance member 804 is integrally formed with the first portion 150w. In other embodiments, the resistance member can be integrally formed with the second portion 152w. In still other embodiments, the resistance member can be separately formed from and operatively coupled to the first portion 150w and/or

to the second portion 152w. In the embodiment illustrated in Figures 110-119, the resistance member 804 comprises a distally-facing surface of the first portion 150w.

[0657] The system 104w can be configured to couple the on-skin component 134w to the base 128w via an adhesive 806. Figure 115 illustrates a perspective view of the needle hub 162w, shown securing the on-skin component 134w during deployment, with the base 128w removed to illustrate the adhesive 806 disposed on a distally-facing surface of the on-skin component 134w. The adhesive 806 can be configured to couple the on-skin component 134w to the base 128w on contact. Alternatively or in addition to the adhesive 806, some embodiments can include an adhesive disposed on a proximally-facing surface of the base, so as to couple the on-skin component to the base upon contact. In some embodiments, the adhesive can be a pressure-sensitive adhesive. In some embodiments, the securement member can be configured to couple the on-skin component to the needle hub only along a plane extending normal to the axial direction of the system. In addition or in the alternative, the securement can be configured to couple the on-skin component in a lateral or radial direction.

[0658] Figure 116 illustrates another perspective view of the needle hub 162w, shown decoupled from the on-skin component 134w, with the base 128w removed to illustrate the adhesive 808 disposed on the distally-facing surfaces of the securement member 800. The adhesive 808 can be configured to couple the on-skin component 134w to the securement member 800 while in the proximal starting position and during movement of the on-skin component 134w in the proximal direction, and to allow the release of the on-skin component 134w from the securement member 800 after the on-skin component 134w is coupled to the base 128w. Alternatively or in addition to the adhesive 808, some embodiments can include an adhesive disposed on a proximally-facing surface of the on-skin component 134w. In some embodiments, the adhesive can be a pressure-sensitive adhesive. In some embodiments, the adhesive 808 can have a smaller surface area and/or a lower adhesion strength than the adhesive 806, such that the adhesion strength of the adhesive 806 which couples the on-skin component to the base outweighs the adhesion strength of the adhesive 808 which couples the on-skin component to the securement member. In other embodiments, the adhesion strength of the adhesive 808 can be the same or greater than the adhesion strength of the adhesive 806. In these embodiments, a resistance member can be employed to facilitate the decoupling of the on-skin component 134w from the securement member 800 after deployment.

[0659] Figure 117 illustrates a perspective view of a portion of the system 104w, illustrating the resistance member 804. The resistance member 804 is configured to rest above and/or contact a proximally-facing surface of the on-skin component 134w, at least when the on-skin component 134w is in a distal deployed position. The resistance member 804 can serve to inhibit proximal movement of the on-skin component 134w as the needle hub 162w and securement member 800 retract in a proximal direction. The resistance member 804 can function in a manner similar to a stripper plate in punch and die manufacturing or injection molding processes.

[0660] In embodiments, the resistance member can have any configuration suitable for resisting decoupling of the on-skin component from the base. In the embodiment illustrated in Figures 110-119, the resistance member 804 has a curvilinear cross section, and extends through an arc of roughly 300 degrees about the perimeter of the on-skin component 134w. In some embodiments, the resistance member 804 can extend through an arc of roughly 30 degrees, 60 degrees, 90 degrees, 120 degrees, 150 degrees, 180 degrees, 210 degrees, 240 degrees, 270 degrees, 300 degrees, or 330 degrees about the perimeter of the on-skin component 134w, or through an arc greater than, less than, or within a range defined by any of these numbers. In some embodiments, the resistance member 804 can extend continuously or discontinuously about the perimeter of the on-skin component. In some embodiments, the resistance member 804 can extend about the entire perimeter of the on-skin component. In some embodiments, the resistance member 804 can comprise one or more contact points or surfaces that hold the on-skin component 134w in the distal position as the securement feature 800 moves in an opposite (e.g., proximal) direction.

[0661] In other embodiments, the resistance member 804 can comprise multiple discrete members (e.g., legs) configured to contact multiple locations about the perimeter of the on-skin component 134w. For example, in some embodiments, the resistance member 804 can include at least two legs disposed apart from one another about a center point of the on-skin component. In some embodiments, the resistance member 804 can include two legs disposed roughly 180 degrees about a center point of the on-skin component. In some embodiments, the resistance member 804 can include three legs disposed roughly 120 degrees about a center point of the on-skin component. In such an embodiment, the legs can be arranged symmetrically about the on-skin component (e.g. with radial symmetry, or reflectional/bilateral symmetry).

[0662] Figure 117 also illustrates locator features 810 which can be formed in, or integrally coupled to, the first portion 150w and/or the resistance member 804. The locator features 810 can comprise distally-extending tabs of the first portion 150w and/or of the resistance member 804. The locator features 810 can be configured to align with corresponding indentations 812 in the on-skin component (see Figure 119) so as to ensure proper positioning of the sensor module 134w with respect to the first portion 150w and/or the resistance member 804 during assembly.

[0663] Figure 118 illustrates a perspective view of the sensor module 134w, before being coupled to the base 128w by contacting the adhesive 806. The base 128w itself is coupled (for example by an adhesive) to a proximal surface of an adhesive patch 900. Figure 119 illustrates a perspective view of the sensor module 134w after being coupled to the base 128w on the adhesive patch 900.

[0664] In embodiments, providing a resistance member can facilitate a reliable transfer of the on-skin component to the base, by creating a counterforce against the securement member as the needle hub retracts in the proximal direction. The counterforce allows the securement member to separate from the on-skin component while inhibiting or preventing the disengagement of the on-skin component from the base (if any) and/or from the adhesive patch. In embodiments, the retraction spring can be configured to store and provide sufficient energy to both retract the needle and decouple the on-skin component from the needle hub. The combination of the resistance member and securement member can also be configured to provide positional control of the on-skin component from a secured configuration (e.g., in the proximal starting position and during movement of the on-skin component toward the distal deployed position) to a released configuration (when the on-skin component reaches the distal deployed position and/or couples to the base and/or adhesive patch).

[0665] It is contemplated that providing a base which begins in the distal deployed position when the system is in a resting or stored state can serve to protect the needle (and the user) before the system is deployed. For example, a base which is coupled to a distal end of the system in a resting or pre-deployment state can prevent a user from reaching into the distal end of the system and pricking him or herself. This configuration can thus potentially reduce needle stick hazards. In addition, a base which is coupled to a distal end of the system in a resting or pre-deployment state facilitate the setting of the adhesive patch on the skin before deployment.

For example, with such a configuration, the user can use the body of the sensor inserter system to assist in applying a force in a distal direction to adhere the adhesive patch to the skin. In addition, the base can provide structural support to guide the needle into the skin during deployment.

[0666] Figures 120-122 illustrate another configuration for coupling an on-skin component to a base, in accordance with several embodiments. Figure 120 shows a side view of an on-skin component 134x and a base 128x, prior to coupling of the on-skin component 134x to the base 128x. The on-skin component 134x includes a distally-extending sensor 138, and the base 128x is coupled to an adhesive patch 900. Figure 121 illustrates a perspective view of these same components. The base 128x comprises a flexible elastomeric member with a proximally-extending ridge 814 extending about a proximally-facing surface 816. The base 128x can have a shape configured to correspond to a shape of the on-skin component 134x. In a relaxed state, as illustrated in Figures 120 and 121, and before making contact with the on-skin component 134x, the base 128x has a deformed, somewhat convex curvature. The base 128x and the adhesive patch 900 can be coupled to the other components of a sensor inserter assembly in this configuration. During deployment, as the on-skin component 134x begins to contact the base 128x, the proximally-facing surface 816 flexes up to meet the distal surface of the on-skin component 134x, causing the ridge 814 to grip securely about the perimeter of the on-skin component 134x, as illustrated in Figure 122.

[0667] Figure 123 illustrates a perspective view of a portion of another inserter system 104y, according to some embodiments. The system 104y can be configured substantially similar to any of the systems 104 illustrated herein, with like reference numerals indicating like parts. The inserter system 104y includes an on-skin component 134y which includes a combination sensor module and base. In embodiments, the combination sensor module and base can be integrally formed with one another, as illustrated in Figure 123, or operatively coupled to one another. The system 104y also includes a securement member 800y which is configured to releasably secure the on-skin component 134y in a proximal starting position, at least until the system 104y is activated. The securement member 800y is integrally formed with the needle hub 162y, and includes three proximally-extending legs 802y configured to releasably couple to (e.g. via adhesive 808) various locations on the proximal surface of the on-skin component 134y. It is contemplated that the addition of a third (or further) leg 802y can help to balance the sensor

module and prevent it from canting to one side or another during deployment and/or retraction. The system 104y also includes a resistance member 804. The resistance member 804 may be integrally molded with first portion 150y.

[0668] Figure 124 illustrates another perspective view of the on-skin component 134y and the needle hub 162y, with the remainder of the system 104y removed to illustrate the configuration of the securement member 800y. Figure 125 illustrates a perspective view of a portion of the applicator system shown in Figure 123, with the on-skin component 134y in a released configuration and separated from the needle hub 162y and with two of the legs 802y removed for purposes of illustration. The resistance member 804y can be configured to encompass or at least partially encompass the sensor module portion of the on-skin component 134y. The resistance member 804y can comprise one or more elongate members, columns, legs, and/or protrusions, or can have any other suitable configuration for facilitating the release of the on-skin component from the needle hub 162y. The resistance member 804y (or any portion thereof) can have a curvilinear cross section, as illustrated in Figure 125, or can have any other suitable cross section, including circular, square, triangular, ovoid, L-shaped, O-shaped, U-shaped, V-shaped, X-shaped, or any other regular or irregular shape or combination of shapes.

[0669] As shown in Figure 125, the system 104y can include an adhesive patch 818 disposed on the distally-facing surface of the on-skin component 134y. The adhesive patch 818 can be configured to couple the on-skin component 134y to the skin on contact. In some embodiments, the adhesive patch can be a pressure-sensitive adhesive. In some embodiments, the adhesive patch 818 is a double sided adhesive, in which an adhesive is disposed on both the proximally facing surface of the adhesive patch 818 and the distally facing surface of the adhesive patch 818. The proximally facing adhesive can be configured to couple with the distal end of the on-skin component 134y, and the distally facing adhesive can be configured to couple with the skin. In other embodiments, the proximally facing surface of the adhesive patch 818 is configured to couple with the distally facing surface of the on-skin component by a coupling process such as, but not limited to, heat staking, fastening, welding, or bonding. In some embodiments, the adhesive patch 818 can be covered by a removable liner prior to deployment. In other embodiments, the adhesive patch 818 can be exposed (e.g., uncovered) within the system prior to deployment.

[0670] Alternatively, in some embodiments the adhesive patch 818 can be releasably secured to the distal end of the system before deployment, with an adhesive disposed on a proximally-facing surface of the adhesive patch 818, so as to couple the on-skin component to the adhesive patch 818 upon contact as part of the sensor insertion process. In addition, in such an embodiment, the adhesive patch 818 can include an adhesive disposed on a distally-facing surface of the adhesive patch 818 to couple the on-skin component to the skin.

[0671] Such a configuration can include fewer components to be coupled and decoupled during the deployment and insertion process, which can increase reliability of systems configured in accordance with embodiments. For example, systems configured in accordance with embodiments can reduce the chance of improper transfer of system components to the skin. In addition, it is contemplated that embodiments comprising an adhesive patch disposed within the system in a resting state (as opposed to an adhesive patch disposed at a distal end of the system in the resting state) can allow for the system to be more easily re-positioned on the skin as many times as desired before being adhered to the skin.

[0672] Figures 126-128 illustrate another configuration for releasably securing an on-skin component in a proximal position, in accordance with several embodiments. Figure 126 illustrates a perspective view of a portion of a securement member 800z shown secured to an on-skin component 134z comprising a sensor module. The securement member 800z can include at least one leg 802z. As shown in the figure, the securement member 800z includes two proximally-extending legs 802z. The on-skin component 134z includes two elastomeric grips 824 extending laterally from the sensor module. The grips 824 are sized and shaped to cooperate with laterally-facing surfaces of the legs 802z to releasably secure the on-skin component 134z in a proximal position. In the embodiment illustrated in Figures 126-128, the grips 824 are integrally formed with the sensor module, and have a bracket-shaped cross section, as viewed in a plane extending normal to the axial direction. In embodiments, the securement member 800z and the grips 824 can have any suitable cooperating configuration to allow the on-skin component 134z to releasably couple the securement member 800z to the grips 824, for example via a friction fit, interference fit, or corresponding undercut engagement features. Some embodiments can additionally employ an adhesive disposed between the securement member 800z and the on-skin component 134z, to provide additional securement of the on-skin component 134z.

[0673] Figure 127 illustrates a perspective view of a portion of the securement member 800z, with the sensor module of the on-skin component 134z shown in cross section to illustrate the configuration of the grips 824. Figure 127 also shows a decoupling feature 804z configured to resist proximal movement of the on-skin component 134z after deployment of the on-skin component 134z to the distal deployed position, for example during retraction of the needle hub 162z. The decoupling feature 804z can be fixed with respect to the remainder of the sensor inserter system as the needle hub 162z retracts in a proximal direction, providing enough resistance to overcome the friction fit (and adhesive, if any) between the securement member 800z and the grips 824 to release the securement member 800z from the grips 824. Figure 128 illustrates a perspective view of the on-skin component 134z, after decoupling of the on-skin component 134z from the securing member 800z.

[0674] Figures 129-131 illustrate still another configuration for releasably securing an on-skin component, in accordance with several embodiments. Figure 129 illustrates a perspective view of a portion of a sensor inserter assembly 104aa with the second portion 150aa shown in cross section, and with a securing member 800aa shown securing an on-skin component 134aa in a proximal position. The on-skin component 134aa may comprise an integrally formed sensor module/base assembly. As shown in the figure, the securement member 800aa comprises an elastomeric cap which is coupled to a portion of the on-skin component 134aa. As shown, the securement member 800aa can be coupled to a protrusion (or neck) 826 formed in the on-skin component 134aa. Figure 130 illustrates a perspective view of a portion of the assembly 104aa of Figure 129, shown with a portion of the securing member 800aa cut away to better illustrate the configuration of the securing member 800aa and the protrusion 826. The protrusion 826 can be configured to encircle, or at least partially encircle, the needle 158 when it extends in a proximal direction through the on-skin component 134aa. The protrusion 826 can also be configured to secure the securement member 800aa to the on-skin component 134aa. The securement member 800aa has an opening 828 which is sized and shaped to create a friction fit between the opening 828 and the needle 158. In the configuration illustrated in Figures 129 and 130, with the needle 158 extending distally through the securement member 800aa and the protrusion 826, the friction fit between the securement member 800aa and the needle 158 serves to resist at least distal movement of the on-skin component 134aa with respect to the needle 158.

[0675] The embodiment illustrated in Figures 129-131 may also include a resistance member 804aa. The resistance member may be substantially similar to any resistance member described in Figures 110-128. The resistance member 804aa can include a distally-facing surface of the first portion 150aa, and can have a similar configuration to the resistance member 804 described in the context of Figure 117. The resistance member 804aa can provide enough resistance in a distal direction to allow the second spring and needle hub (not shown) to overcome the friction fit between the securement member 800aa and the needle 158. It is contemplated that this would allow the needle 158 to retract away from the skin and at the same time allow the needle to decouple from the securement member 800aa. Figure 131 illustrates a perspective view of a portion of the assembly 104aa, after decoupling of the on-skin component 134aa from the needle 158, shown with the protrusion 826 of the on-skin component 134aa and the securing member 800aa cut away for purposes of illustration.

[0676] Figures 132-133 illustrate another configuration for releasably securing an on-skin component in a proximal position, in accordance with several embodiments. Figure 132 illustrates a perspective view of a portion of a securement member 800ab shown secured to an on-skin component 134ab comprising a sensor module, with the second portion 150ab shown in cross section. The securement member 800ab may include at least one engagement feature. As shown in the figure, the at least one engagement feature can be two proximally-extending legs 802ab. The on-skin component 134ab may include at least one receiving feature. As shown, the at least one receiving feature can be two elastomeric grips 824ab extending laterally from the on-skin component 134ab. The grips 824ab are deformable and sized and shaped to receive the legs 802ab via friction or interference fit and thereby releasably secure the on-skin component 134ab in a proximal position. In the embodiment illustrated in Figures 132-133, the legs 802ab of the securement member 800ab have a circular cross-section. The grips 824ab are integrally formed with the sensor module, and have an annular-shaped cross section, as viewed in a plane extending normal to the axial direction. The grips 824ab may each include an opening which can be configured to receive the legs 802ab via frictional engagement. In embodiments, the securement member 800ab and the grips 824ab can have any suitable cooperating configuration to releasably couple the securement member 800ab to the grips 824ab. Some embodiments can additionally employ an adhesive disposed axially between the securement member 800ab and the on-skin component 134ab, to provide additional securement of the on-skin component 134ab in

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the proximal starting position. Figure 133 illustrates a perspective view of the needle hub 162ab and the on-skin component 134ab, after decoupling of the on-skin component 134ab from the needle hub 162ab.

[0677] Figures 134-136 illustrate yet another configuration for releasably securing an on-skin component in a proximal position. Figure 134 illustrates an exploded perspective view of a portion of an assembly 134ac, with a securement member 800ac configured to releasably couple an on-skin component 134ac to a needle hub 162ac. The securement member 800ac may include at least one engagement feature. As shown in the figure, the securement member 800ac can include two proximally-extending legs 802ac. The on-skin component 134ac includes two elastomeric grips 824ac extending laterally from the sensor module. The grips 824ac are sized and shaped to receive the legs 802ac in a snap fit to securely hold the on-skin component 134ac in a proximal position. In the embodiment illustrated in Figures 134-136, the legs 802ac of the securement member 800ac have a circular cross-section, with a recessed section 832 configured to receive the grips 824ac. The grips 824ac can be integrally formed with the sensor module, each grip having a frangible link 830 coupling the grips 824ac to the sensor module. The grips 824ac have an annular-shaped cross section, as viewed in a plane extending normal to the axial direction, the grips being configured to receive the recessed sections 832 of the legs in a secure interlocking engagement. In embodiments, the securement member 800ab and the grips 824ab can have any suitable cooperating configuration to securely couple the securement member 800ac to the grips 824ac and prevent slippage of the grips along the legs 802ac as the needle hub 162ac deploys and as it retracts after deployment. Some embodiments can additionally employ an adhesive disposed axially between the securement member 800ac and the on-skin component 134ab, to provide additional securement of the on-skin component 134ac in the proximal starting position and during deployment.

[0678] Figure 135 illustrates a perspective view of a portion of the system 104ac, with the securement member 800ac securely coupled to the on-skin component 134ac. Some embodiments can additionally employ an adhesive disposed axially between the securement member 800ac and the on-skin component 134ac, to provide additional securement of the on-skin component 134ac in the proximal starting position. The frangible links 830 are configured to shear or otherwise detach upon application of a minimum threshold of force, as the needle hub 162 retracts in a proximal direction after deployment, separating the grips 824ac from the

remainder of the on-skin component 134ac and leaving the on-skin component 824ac in the deployed distal position. Figure 136 illustrates a perspective view of a portion of the system 104ac, with the frangible links 830 broken and the securement member 800ac decoupled from the on-skin component 134ac. In some embodiments, a resistance member can also be employed to prevent proximal movement of the on-skin component 134ac as the needle hub 162ac retracts, facilitating the breakage of the frangible links 830.

[0679] Frangible couplings can also be employed between an on-skin component and the second portion of a sensor inserter system to releasably secure the on-skin component in a proximal starting position prior to deployment. For example, Figures 137-140 illustrate various perspective views of a sensor inserter system 104ad with an on-skin component 134ad releasably secured in a proximal position within the system 104ad. The on-skin component 134ad can include a combination sensor module and base disposed on an adhesive patch 900ad. To facilitate in releasably securing the on-skin component 134ad to the second portion 152ad, the second portion 152ad can include at least one distally-extending protrusion 834. As shown in the figure, the second portion 152ad includes four distally-extending protrusions 834 configured to securely couple with corresponding sockets 836 formed in or otherwise extending from the adhesive patch 900ad. The sockets 836 are connected to the adhesive patch 900ad via frangible links 838, which can also be integrally formed in the adhesive patch 900ad. In the resting state illustrated in Figure 137, the adhesive patch 900ad is secured in a proximal position by the coupling of the sockets 836 to the posts 838. As the system 104ad is deployed and a force is applied to the on-skin component 134ad in a distal direction, the frangible links 838 detach, allowing the adhesive patch 900ad (and the on-skin component 134ad which is already coupled thereto) to move to the distal deployed position. Figure 138 illustrates a perspective view of the sensor inserter system 104ad, with the frangible links 838 detached and the adhesive patch 900ad released from securement. Figures 139 and 140 illustrate perspective views of the adhesive patch 900ad and the on-skin component 134ad, with the frangible links 838 in intact and detached configurations, respectively. Once the frangible links 838 are detached and the on-skin component 134ad (along with the patch 900ad) is deployed in the distal position, the remainder of the system 104ad can easily be lifted off the skin of the host and removed.

[0680] Figure 141 illustrates another configuration for releasably securing a base and adhesive patch to a sensor inserter assembly. Figure 141 illustrates a cross-sectional perspective

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view of a portion of a system 104ae, with the first portion 150ae, the second portion 152ae, and the third portion 392ae shown in cross section. The system 104ae includes an on-skin component 134ae which is releasably secured in a proximal starting position. The system 104ae also includes a base 128ae coupled to an adhesive patch 900ae. The base 128ae and the adhesive patch 900ae are disposed in a distal position, at a distal end of the system 104ae. The base 128ae is coupled to the system 104ae via a plurality of ribs 840 extending radially inward from the second portion 152ae. The ribs 840 can be sized and shaped to grip the edges of the base 128ae with a friction/interference fit. The friction/interference fit between the ribs 840 and the base 128ae can be configured to be strong enough to securely couple the base 128ae to the system 104ae during storage and prior to deployment, but weak enough that the adhesive coupling between the adhesive patch 900ae and the skin of the host overcomes the strength of the friction fit. Thus, once the adhesive patch 900ae is adhered to the skin of the host, the second portion 152ae can be lifted off the base 128ae and the sensor system 104ae can be removed without pulling the base 128 in a proximal direction. In some embodiments, the base 128ae may comprise an elastomeric material. Further, in some embodiments, the base 128ae may have a hardness value less than a hardness value of the on-skin component 134ae. In other embodiments, the base 128ae may have a hardness value more than a hardness value of the on-skin component 134ae.

[0681] Figures 142 and 143 illustrate yet another configuration for releasably securing an adhesive patch, optionally including a base, to a sensor inserter system. Figure 142 shows a sensor inserter system 104af with an adhesive patch 900af coupled to the second portion 152af of the system 104af. Figure 143 shows the system 104af with the patch 900af separated from the second portion 152af. As shown in Figure 143, the second portion 152af includes a plurality of adhesive dots 842 disposed on a distally-facing surface or edge of the second portion 152af. The adhesive dots 842 can be configured to be strong enough to securely couple the adhesive patch 900af (and base, if any) to the system 104af during storage and prior to deployment, but weak enough that the adhesive coupling between the adhesive patch 900af and the skin of the host overcomes the strength of the adhesive dots 842. Thus, once the adhesive patch 900af is adhered to the skin of the host, the second portion 152af can be lifted off the applicator patch 900af (and base, if any) and the sensor system 104af can be removed without pulling the adhesive patch 900af (or base, if any) in a proximal direction. Alternatively or in addition to the adhesive dots

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842, some embodiments can include an adhesive disposed on a proximally-facing surface of the adhesive patch 900af. In some embodiments, the adhesive can be a pressure-sensitive adhesive.

INTERPRETATION

[0682] For ease of explanation and illustration, in some instances the detailed description describes exemplary systems and methods in terms of a continuous glucose monitoring environment; however it should be understood that the scope of the invention is not limited to that particular environment, and that one skilled in the art will appreciate that the systems and methods described herein can be embodied in various forms. Accordingly any structural and/or functional details disclosed herein are not to be interpreted as limiting the systems and methods, but rather are provided as attributes of a representative embodiment and/or arrangement for teaching one skilled in the art one or more ways to implement the systems and methods, which may be advantageous in other contexts.

[0683] For example, and without limitation, described monitoring systems and methods may include sensors that measure the concentration of one or more analytes (for instance glucose, lactate, potassium, pH, cholesterol, isoprene, and/or hemoglobin) and/or other blood or bodily fluid constituents of or relevant to a host and/or another party.

[0684] By way of example, and without limitation, monitoring system and method embodiments described herein may include finger-stick blood sampling, blood analyte test strips, non-invasive sensors, wearable monitors (e.g. smart bracelets, smart watches, smart rings, smart necklaces or pendants, workout monitors, fitness monitors, health and/or medical monitors, clip-on monitors, and the like), adhesive sensors, smart textiles and/or clothing incorporating sensors, shoe inserts and/or insoles that include sensors, transdermal (i.e. transcutaneous) sensors, and/or swallowed, inhaled or implantable sensors.

[0685] In some embodiments, and without limitation, monitoring systems and methods may comprise other sensors instead of or in additional to the sensors described herein, such as inertial measurement units including accelerometers, gyroscopes, magnetometers and/or barometers; motion, altitude, position, and/or location sensors; biometric sensors; optical sensors including for instance optical heart rate monitors, photoplethysmogram (PPG)/pulse oximeters, fluorescence monitors, and cameras; wearable electrodes; electrocardiogram (EKG or ECG), electroencephalography (EEG), and/or electromyography (EMG) sensors; chemical sensors; flexible sensors for instance for measuring stretch, displacement, pressure, weight, or impact;

galvanometric sensors, capacitive sensors, electric field sensors, temperature/thermal sensors, microphones, vibration sensors, ultrasound sensors, piezoelectric/piezoresistive sensors, and/or transducers for measuring information of or relevant to a host and/or another party.

[0686] None of the steps described herein is essential or indispensable. Any of the steps can be adjusted or modified. Other or additional steps can be used. Any portion of any of the steps, processes, structures, and/or devices disclosed or illustrated in one embodiment, flowchart, or example in this specification can be combined or used with or instead of any other portion of any of the steps, processes, structures, and/or devices disclosed or illustrated in a different embodiment, flowchart, or example. The embodiments and examples provided herein are not intended to be discrete and separate from each other.

[0687] The section headings and subheadings provided herein are nonlimiting. The section headings and subheadings do not represent or limit the full scope of the embodiments described in the sections to which the headings and subheadings pertain. For example, a section titled "Topic 1" may include embodiments that do not pertain to Topic 1 and embodiments described in other sections may apply to and be combined with embodiments described within the "Topic 1" section.

[0688] Some of the devices, systems, embodiments, and processes use computers. Each of the routines, processes, methods, and algorithms described in the preceding sections may be embodied in, and fully or partially automated by, code modules executed by one or more computers, computer processors, or machines configured to execute computer instructions. The code modules may be stored on any type of non-transitory computer-readable storage medium or tangible computer storage device, such as hard drives, solid state memory, flash memory, optical disc, and/or the like. The processes and algorithms may be implemented partially or wholly in application-specific circuitry. The results of the disclosed processes and process steps may be stored, persistently or otherwise, in any type of non-transitory computer storage such as, for example, volatile or non-volatile storage.

[0689] Any of the features of each embodiment is applicable to all aspects and embodiments identified herein. Moreover, any of the features of an embodiment is independently combinable, partly or wholly with other embodiments described herein in any way, e.g., one, two, or three or more embodiments may be combinable in whole or in part. Further, any of the features of an embodiment may be made optional to other aspects or

embodiments. Any aspect or embodiment of a method can be performed by a system or apparatus of another aspect or embodiment, and any aspect or embodiment of a system can be configured to perform a method of another aspect or embodiment.

[0690] The various features and processes described above may be used independently of one another, or may be combined in various ways. All possible combinations and subcombinations are intended to fall within the scope of this disclosure. In addition, certain method, event, state, or process blocks may be omitted in some implementations. The methods, steps, and processes described herein are also not limited to any particular sequence, and the blocks, steps, or states relating thereto can be performed in other sequences that are appropriate. For example, described tasks or events may be performed in an order other than the order specifically disclosed. Multiple steps may be combined in a single block or state. The example tasks or events may be performed in serial, in parallel, or in some other manner. Tasks or events may be added to or removed from the disclosed example embodiments. The example systems and components described herein may be configured differently than described. For example, elements may be added to, removed from, or rearranged compared to the disclosed example embodiments.

[0691] Conditional language used herein, such as, among others, "can," "could," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or steps. Thus, such conditional language is not generally intended to imply that features, elements and/or steps are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or steps are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Conjunctive language such as the phrase "at least one of X, Y, and Z," unless specifically stated otherwise, is otherwise understood with the context as used in general to convey that an item, term, etc. may be either X, Y, or Z. Thus, such

conjunctive language is not generally intended to imply that certain embodiments require at least one of X, at least one of Y, and at least one of Z to be present.

[0692] The term "and/or" means that "and" applies to some embodiments and "or" applies to some embodiments. Thus, A, B, and/or C can be replaced with A, B, and C written in one sentence and A, B, or C written in another sentence. A, B, and/or C means that some embodiments can include A and B, some embodiments can include A and C, some embodiments can include B and C, some embodiments can only include A, some embodiments can include only B, some embodiments can include only C, and some embodiments can include A, B, and C. The term "and/or" is used to avoid unnecessary redundancy.

[0693] All references cited herein are incorporated herein by reference in their entirety. To the extent publications and patents or patent applications incorporated by reference contradict the disclosure contained in the specification, the specification is intended to supersede and/or take precedence over any such contradictory material.

[0694] Unless otherwise defined, all terms (including technical and scientific terms) are to be given their ordinary and customary meaning to a person of ordinary skill in the art, and are not to be limited to a special or customized meaning unless expressly so defined herein. It should be noted that the use of particular terminology when describing certain features or aspects of the disclosure should not be taken to imply that the terminology is being re-defined herein to be restricted to include any specific characteristics of the features or aspects of the disclosure with which that terminology is associated. Terms and phrases used in this application, and variations thereof, especially in the appended claims, unless otherwise expressly stated, should be construed as open ended as opposed to limiting.

[0695] While certain example embodiments have been described, these embodiments have been presented by way of example only, and are not intended to limit the scope of the inventions disclosed herein. Thus, nothing in the foregoing description is intended to imply that any particular feature, characteristic, step, module, or block is necessary or indispensable. Indeed, the novel methods and systems described herein may be embodied in a variety of other forms; furthermore, various omissions, substitutions, and changes in the form of the methods and systems described herein may be made without departing from the spirit of the inventions disclosed herein.

WHAT IS CLAIMED IS:

1. A system for applying an on-skin sensor assembly to a skin of a host, the system comprising:

a telescoping assembly having a first portion configured to move distally relative to a second portion from a proximal starting position to a distal position along a path;

a sensor module coupled to the first portion, the sensor module including a sensor, electrical contacts, and a seal; and

a base coupled to the second portion such that the base protrudes from a distal end of the system, wherein the base comprises adhesive configured to couple the sensor module to the skin, wherein moving the first portion to the distal position couples the sensor module to the base.

2. The system of Claim 1, wherein the sensor is located within the second portion while the base protrudes from the distal end of the system such that the system is configured to couple the sensor to the base via moving the first portion distally relative to the second portion.

3. The system of Claim 2, wherein the sensor module is coupled to a distal portion of the first portion.

4. The system of Claim 3, wherein the sensor is coupled to the sensor module while the first portion is located in the proximal starting position.

5. The system of Claim 3, further comprising a needle coupled to the first portion such that the sensor and the needle move distally relative to the base and relative to the second portion, the system further comprising a needle release mechanism configured to retract the needle proximally.

6. The system of Claim 1, wherein during a first portion of the path, the sensor module is immobile relative to the first portion, and the base is immobile relative to the second portion.

7. The system of Claim 1, wherein during a second portion of the path, the system is configured to move the first portion distally relative to the second portion to move the sensor module towards the base, to couple the sensor module to the base, and to enable the coupled sensor module and the base to detach from the telescoping assembly.

8. The system of Claim 1, wherein the sensor module comprises a first flex arm that is oriented horizontally and is coupled to the base.

9. The system of Claim 8, wherein the first flex arm extends from an outer perimeter of the sensor module.

10. The system of Claim 8, wherein the base comprises a first proximal protrusion coupled to the first flex arm to couple the sensor module to the base.

11. The system of Claim 1, wherein the base comprises a first flex arm that is oriented horizontally and is coupled to the sensor module.

12. The system of Claim 11, wherein the sensor module comprises a first distal protrusion coupled to the first flex arm to couple the sensor module to the base.

13. An on-skin sensor system configured for transcutaneous monitoring of a host, the system comprising:

a sensor module housing, the sensor module housing including a first flex arm;

a sensor having a first section configured for subcutaneous sensing and a second section mechanically coupled to the sensor module housing;

an electrical interconnect coupled to the sensor module housing and to the sensor; and

a base coupled to the first flex arm of the sensor module housing, the base having an adhesive configured to couple the base to the skin of the host.

14. The system of Claim 13, wherein the electrical interconnect comprises a spring.

15. The system of Claim 14, wherein the sensor module housing comprises at least two proximal protrusions located around a perimeter of the spring, the proximal protrusions are configured to help orient the spring, and a segment of the sensor is located between the proximal protrusions.

16. The system of Claim 13, wherein the first flex arm is oriented horizontally and is coupled to the base.

17. The system of Claim 13, wherein the sensor module housing comprises a proximal protrusion having a channel in which at least a portion of the second section of the sensor is located.

18. The system of Claim 13, further comprising a seal configured to impede fluid ingress to the spring, wherein the spring is a leaf spring.

19. The system of Claim 13, wherein the sensor module housing comprises a channel in which at least a portion of the second section of the sensor is located.

20. The system of Claim 13, wherein the electrical interconnect comprises a compression force of less than one pound over an active compression range.

21. The system of Claim 13, wherein the electrical interconnect comprises a compression force of less than one pound, wherein the compression force is a force necessary to compress the spring 30 percent from a relaxed position.

22. A system for applying an on-skin sensor assembly to a skin of a host, the system comprising:

a telescoping assembly having a first portion configured to move distally relative to a second portion from a proximal starting position to a distal position along a path;

a sensor module coupled to the first portion, the sensor module including a sensor module housing, wherein the sensor module housing includes a first flex arm; and

a base coupled to the second portion such that the base protrudes from a distal end of the system, wherein the base comprises adhesive configured to couple the sensor module to the skin, wherein moving the first portion to the distal position couples the sensor module to the base.

23. The system of Claim 22, wherein the sensor is located within the second portion while the base protrudes from the distal end of the system such that the system is configured to couple the sensor to the base via moving the first portion distally relative to the second portion.

24. The system of Claim 23, wherein the sensor module is coupled to a distal portion of the first portion.

25. The system of Claim 24, wherein the sensor is coupled to the sensor module while the first portion is located in the proximal starting position.

26. The system of Claim 24, further comprising a needle coupled to the first portion such that the sensor and the needle move distally relative to the base and relative to the second portion, the system further comprising a needle release mechanism configured to retract the needle proximally.

27. The system of Claim 21, wherein during a first portion of the path, the sensor module is immobile relative to the first portion, and the base is immobile relative to the second portion, and

28. The system of Claim 21, wherein during a second portion of the path, the system is configured to move the first portion distally relative to the second portion to move the sensor

module towards the base, to couple the sensor module to the base, and to enable the coupled sensor module and the base to detach from the telescoping assembly.

Abbott Ex. 1003 - 445/532

TRANSCUTANEOUS ANALYTE SENSOR SYSTEMS AND METHODS

ABSTRACT

Systems for applying a transcutaneous monitor to a person can include a telescoping assembly, a sensor, and a base with adhesive to couple the sensor to skin. The sensor can be located within the telescoping assembly while the base protrudes from a distal end of the system. The system can be configured to couple the sensor to the base by compressing the telescoping assembly.

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Abbott Ex. 1003 - 446/532

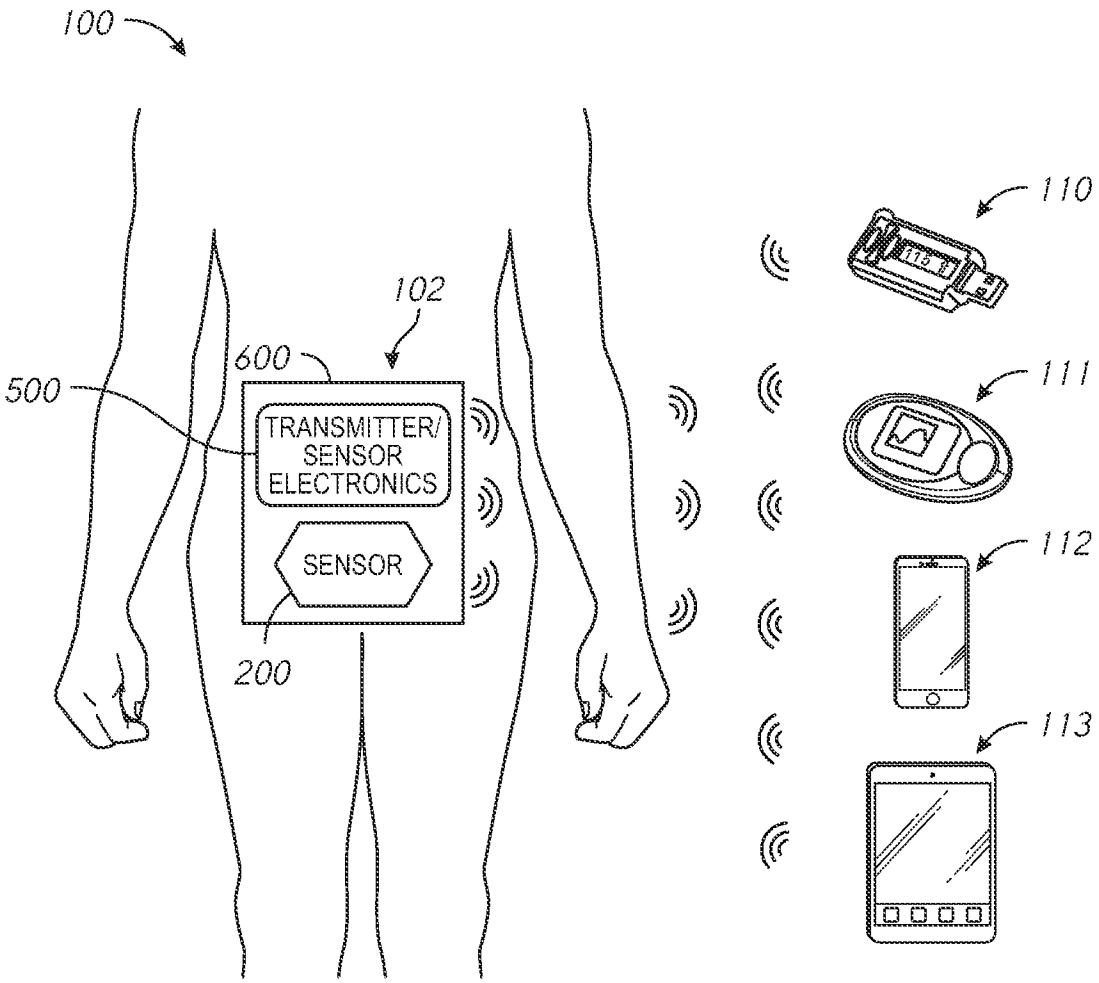

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SENSOR
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FIG. 1

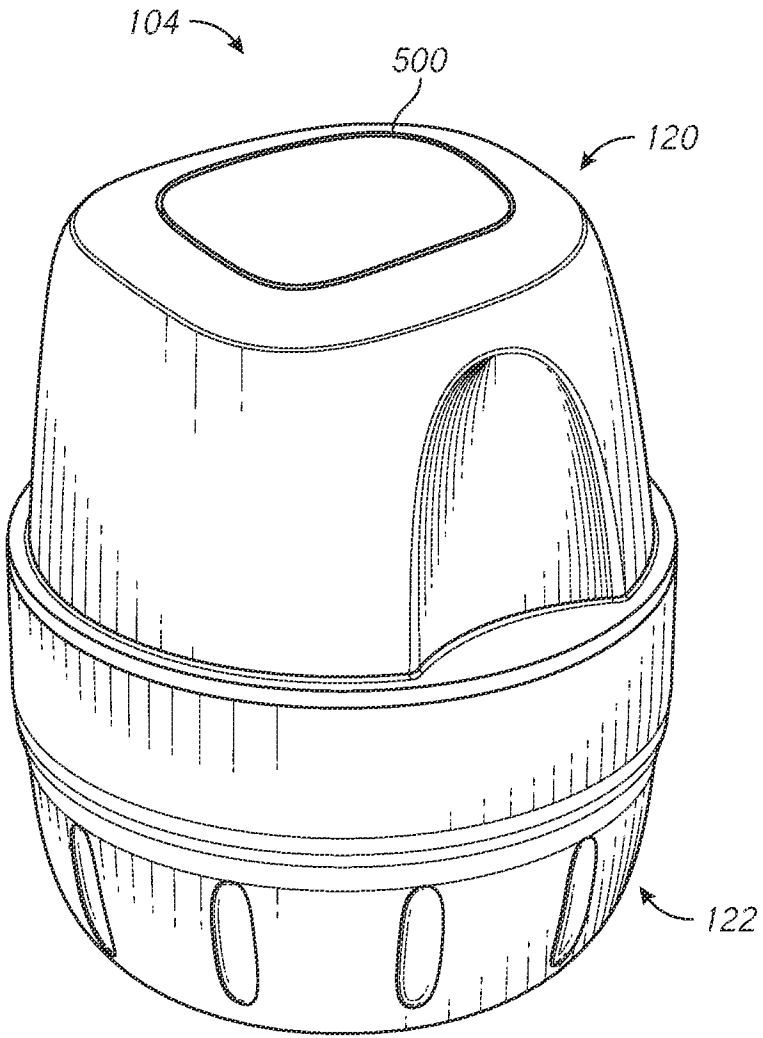

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FIG. 2

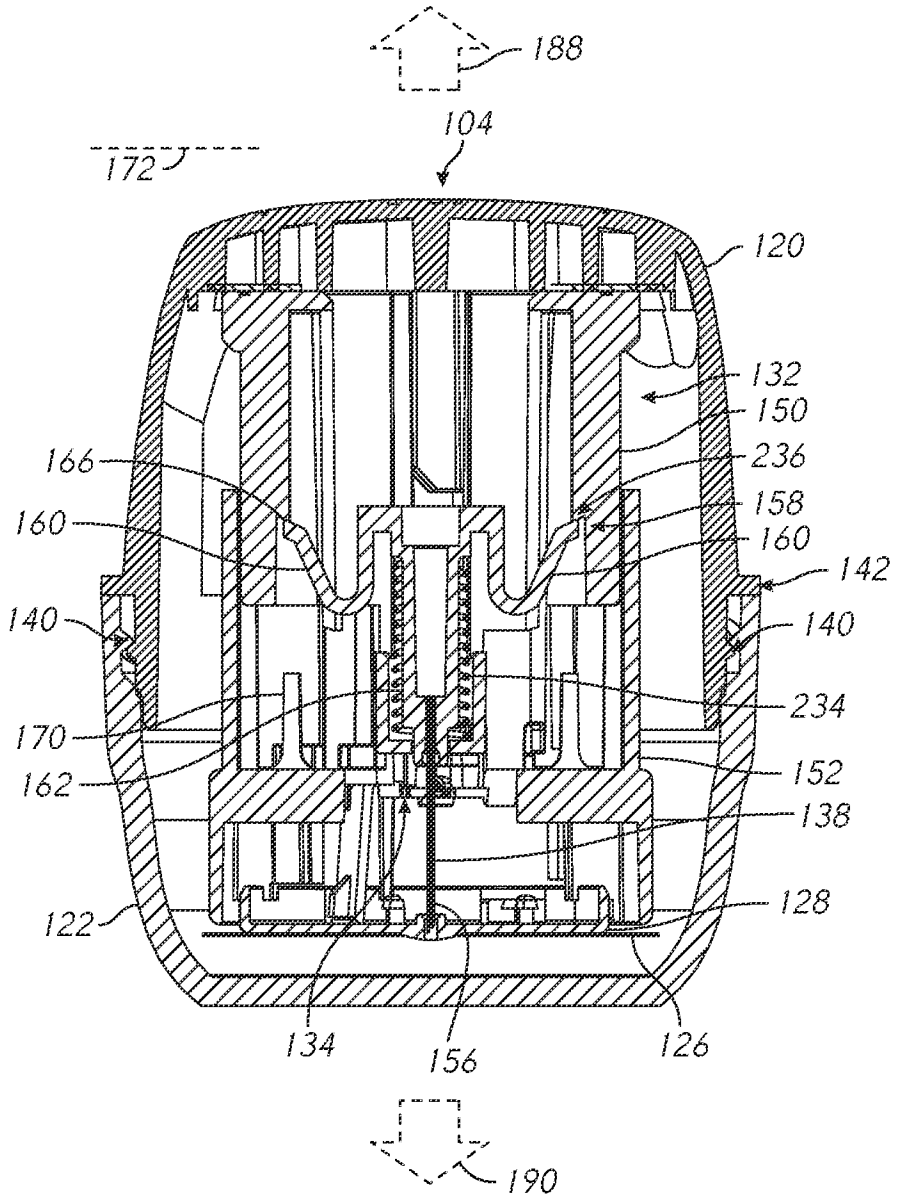

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FIG. 3

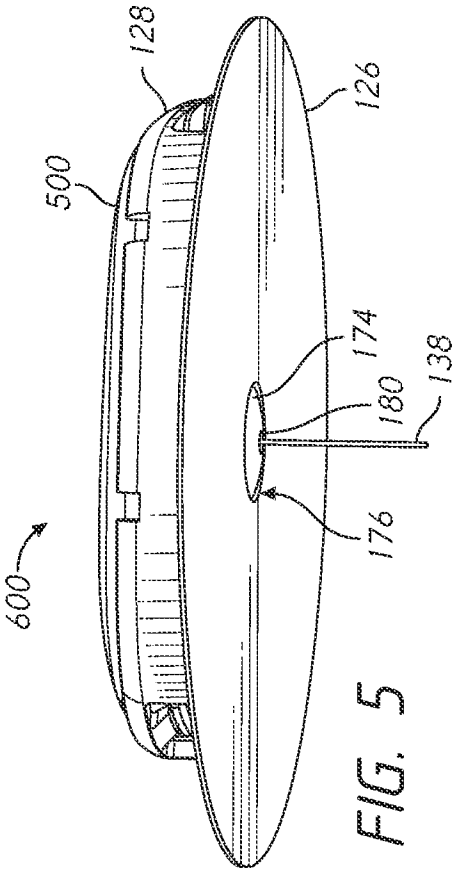


FIG. 5

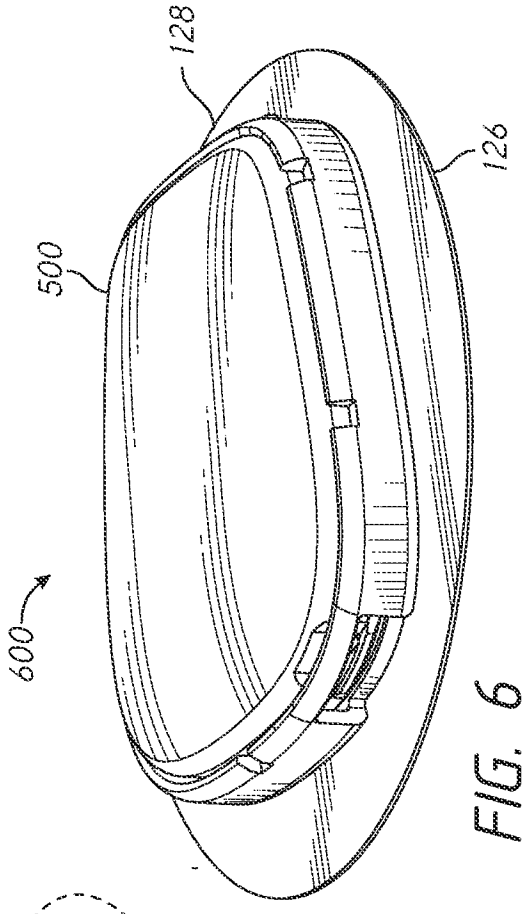


FIG. 6

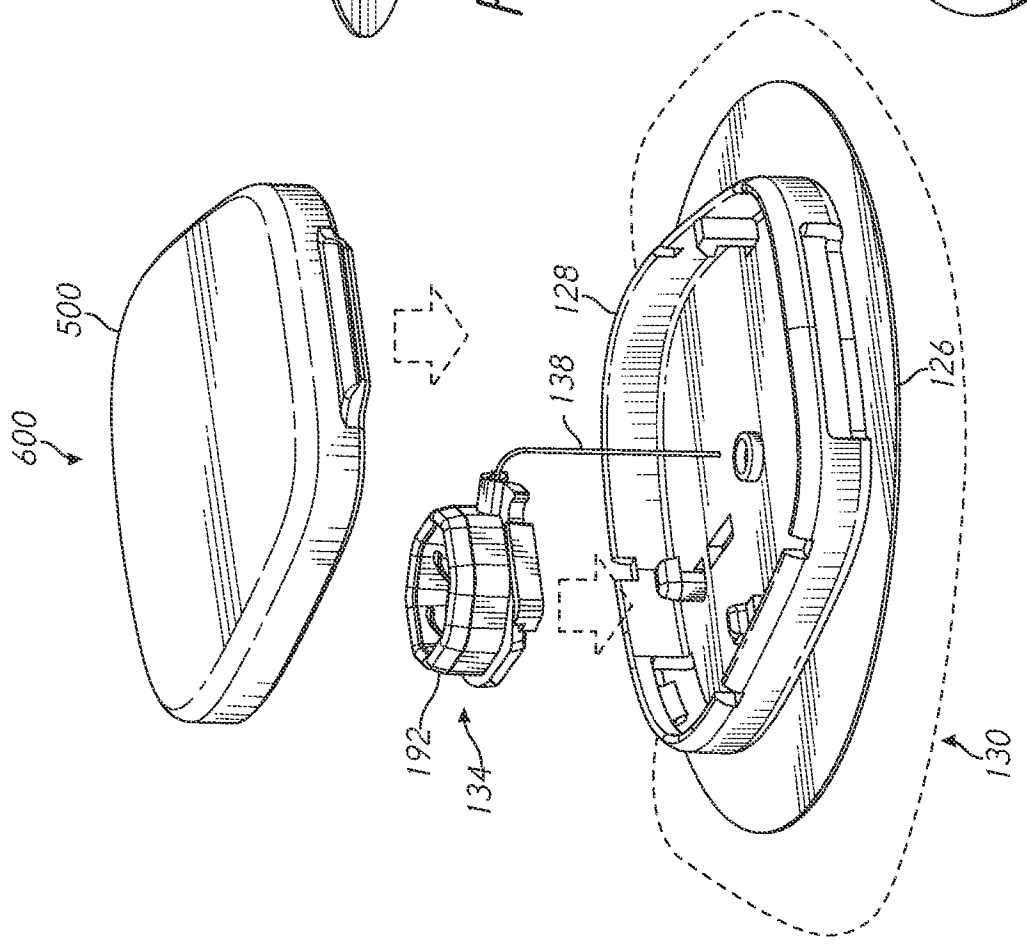


FIG. 4

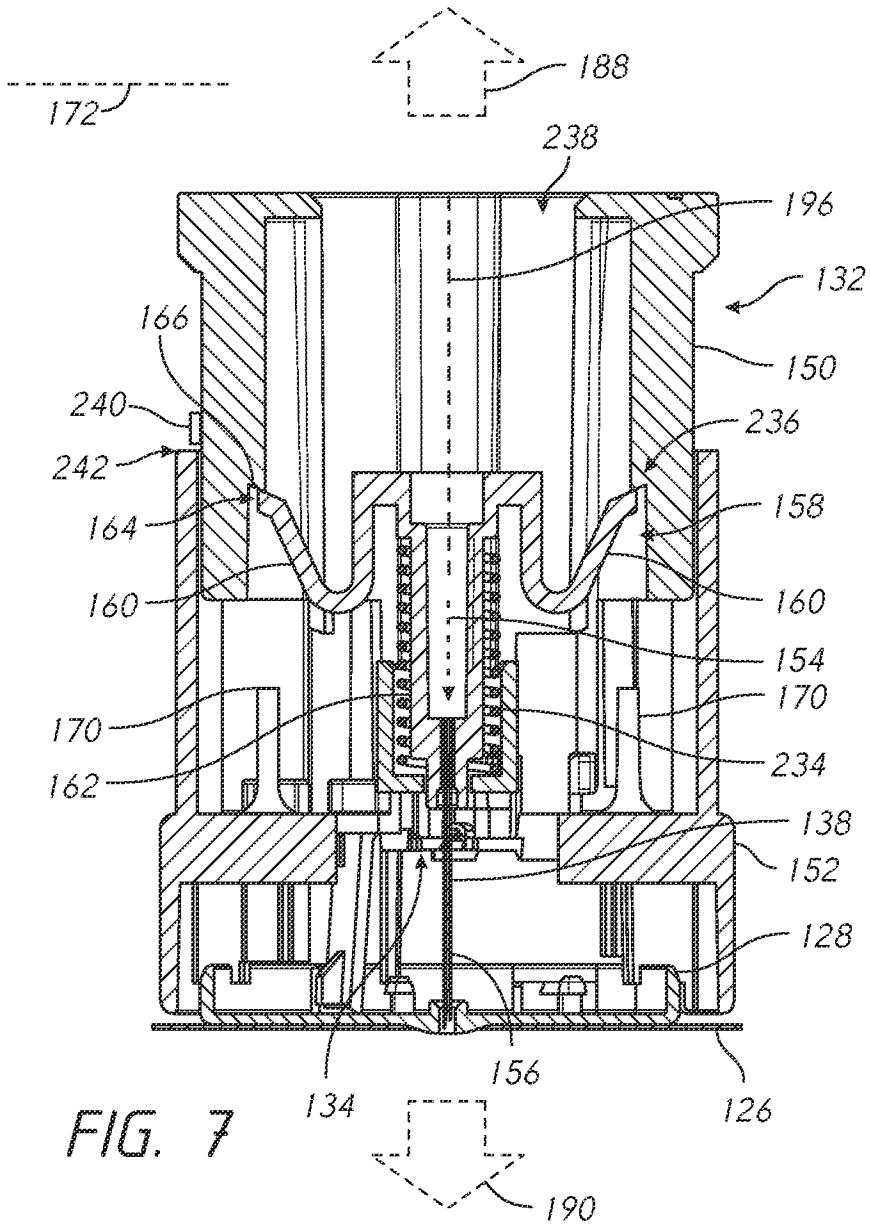

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FIG. 7

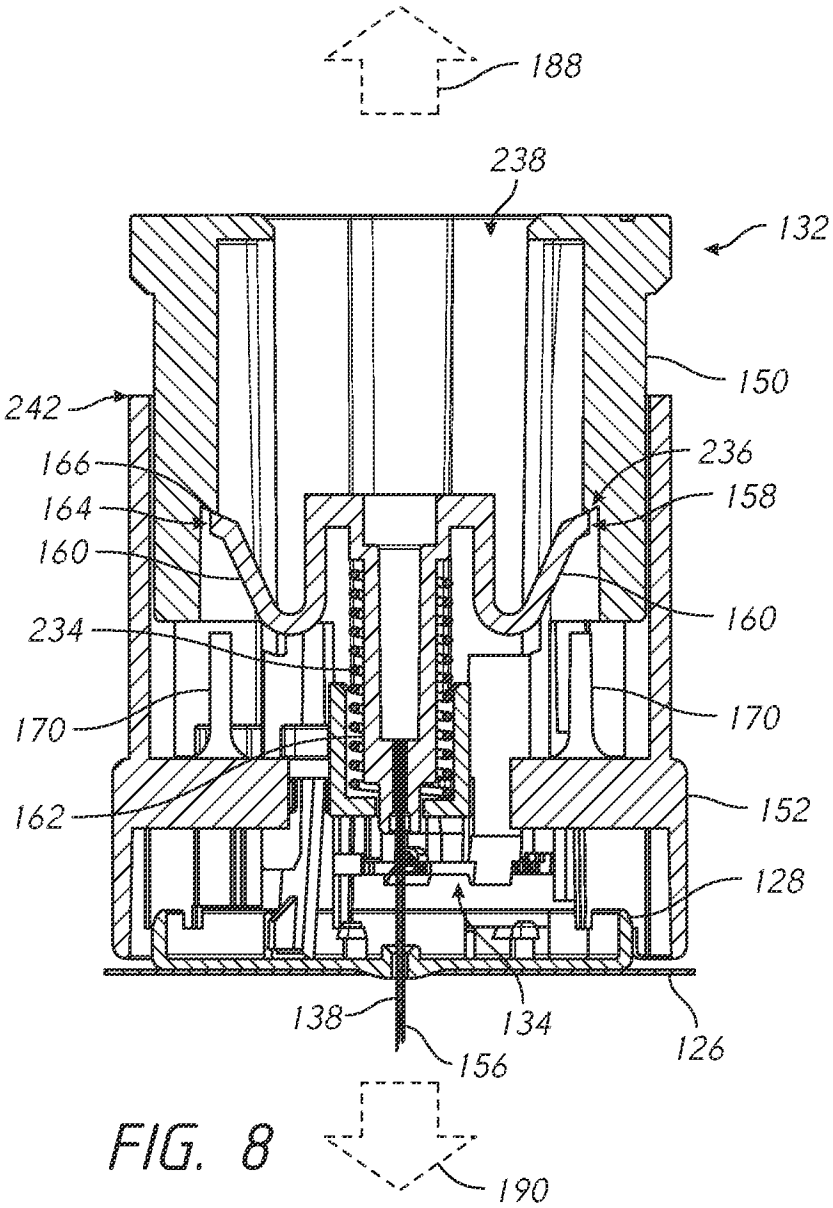

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FIG. 8

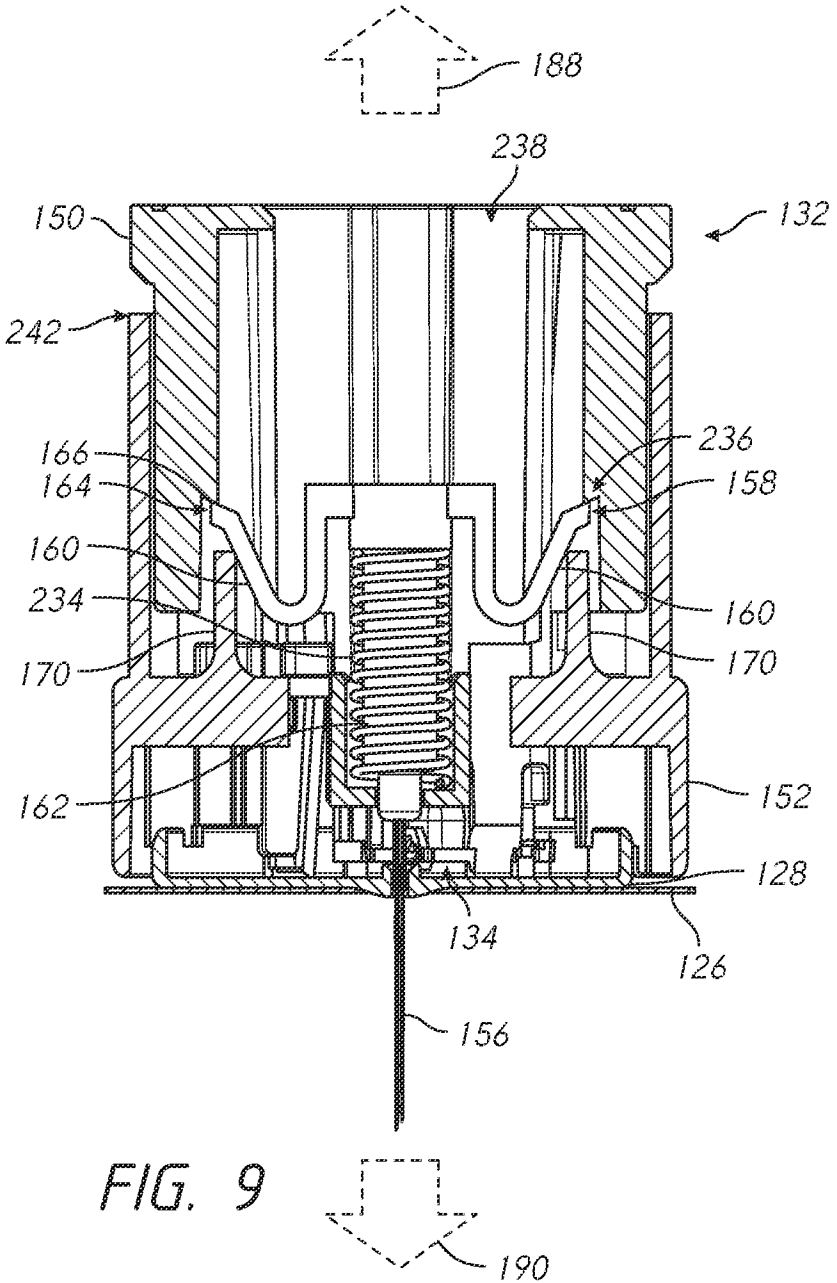

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FIG. 9

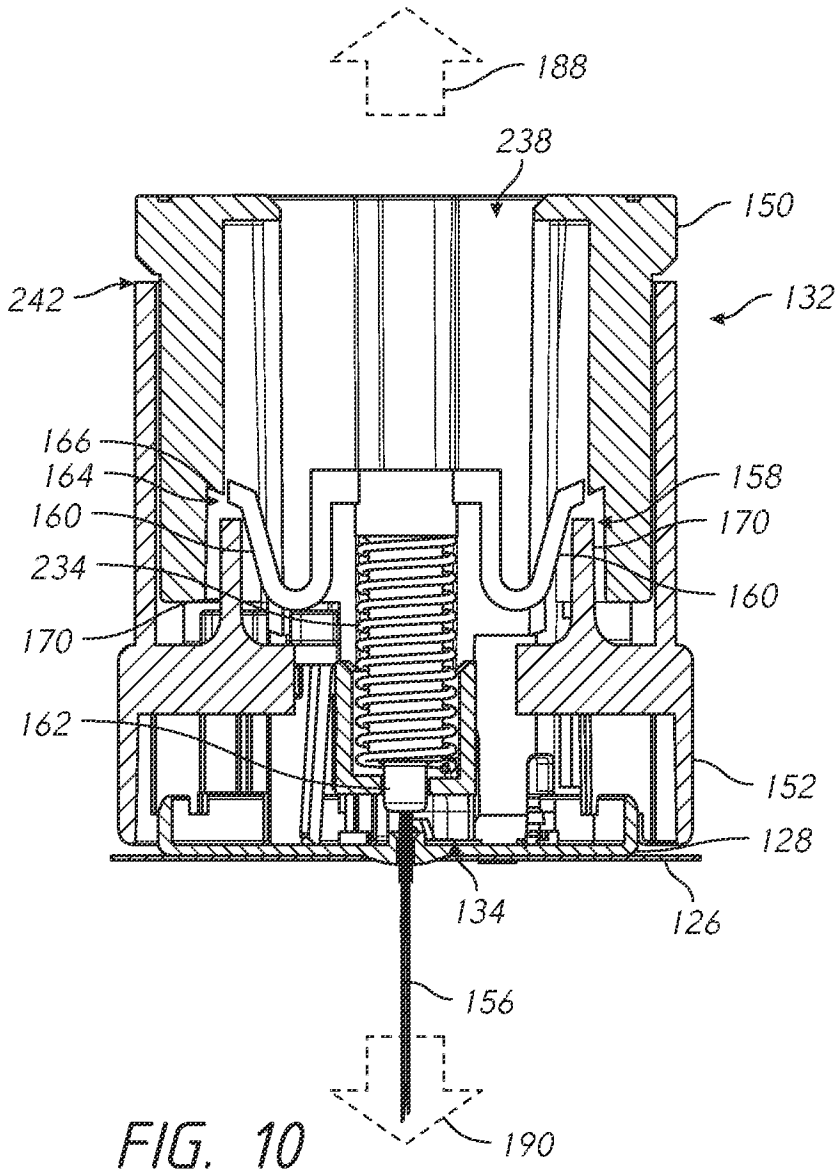

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FIG. 10

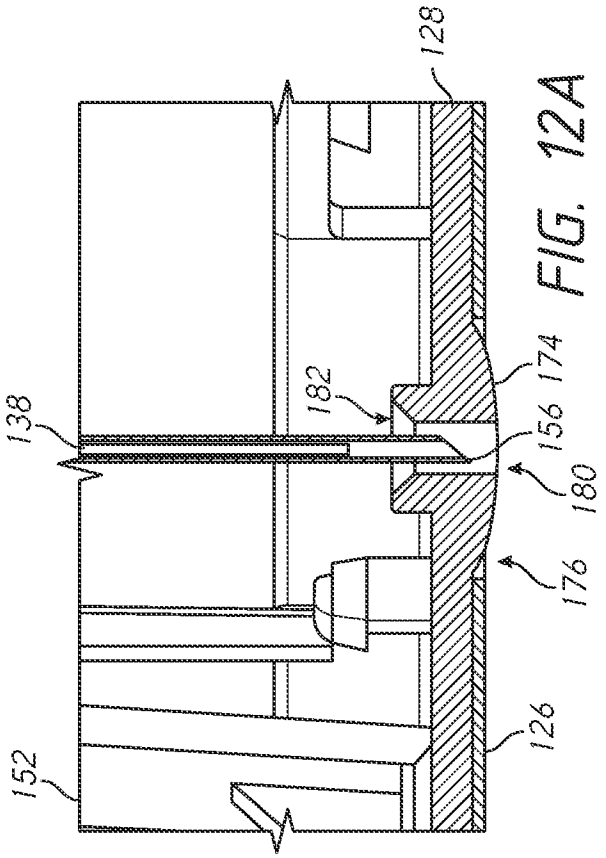


FIG. 12A

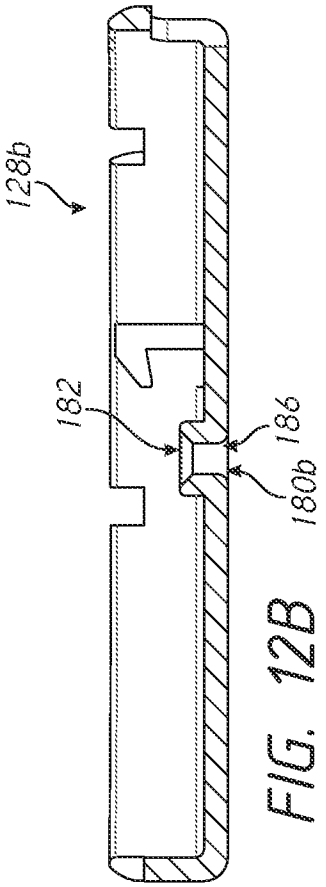


FIG. 12B

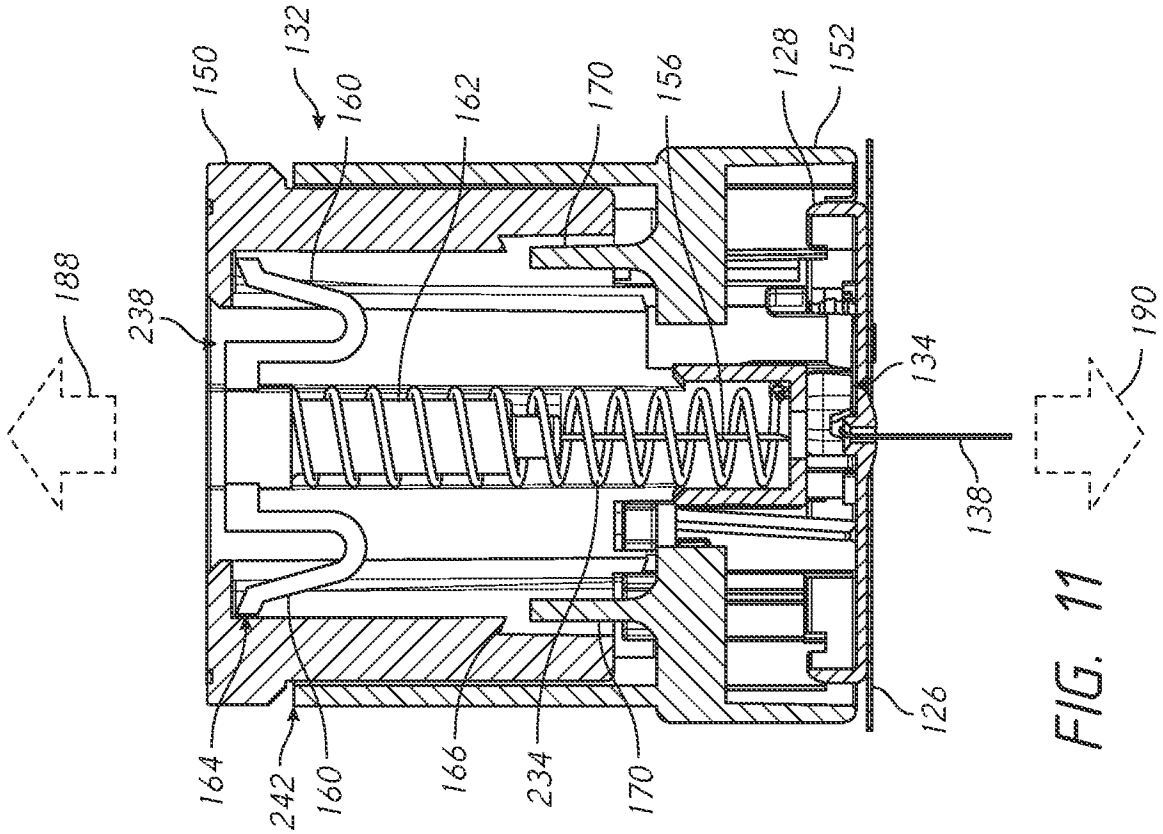


FIG. 11

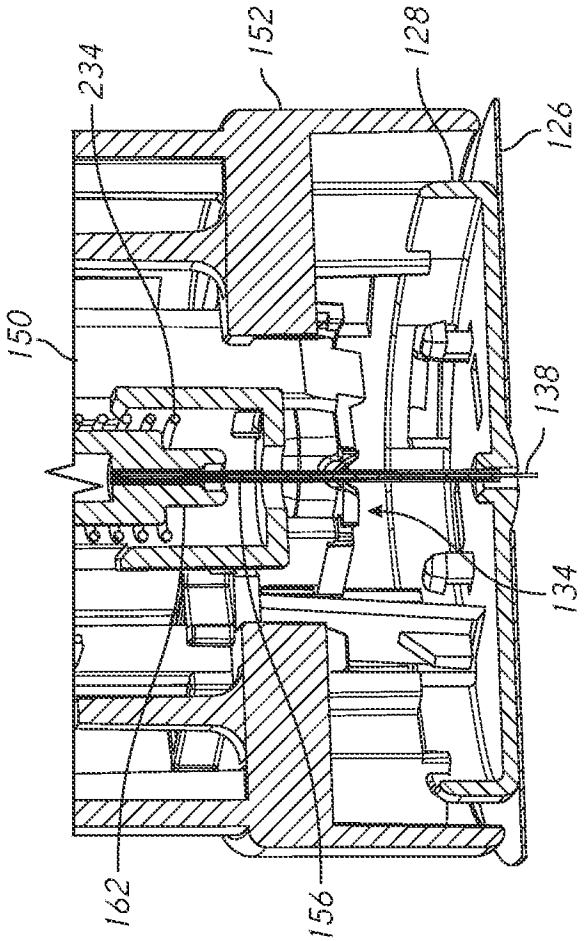

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FIG. 14

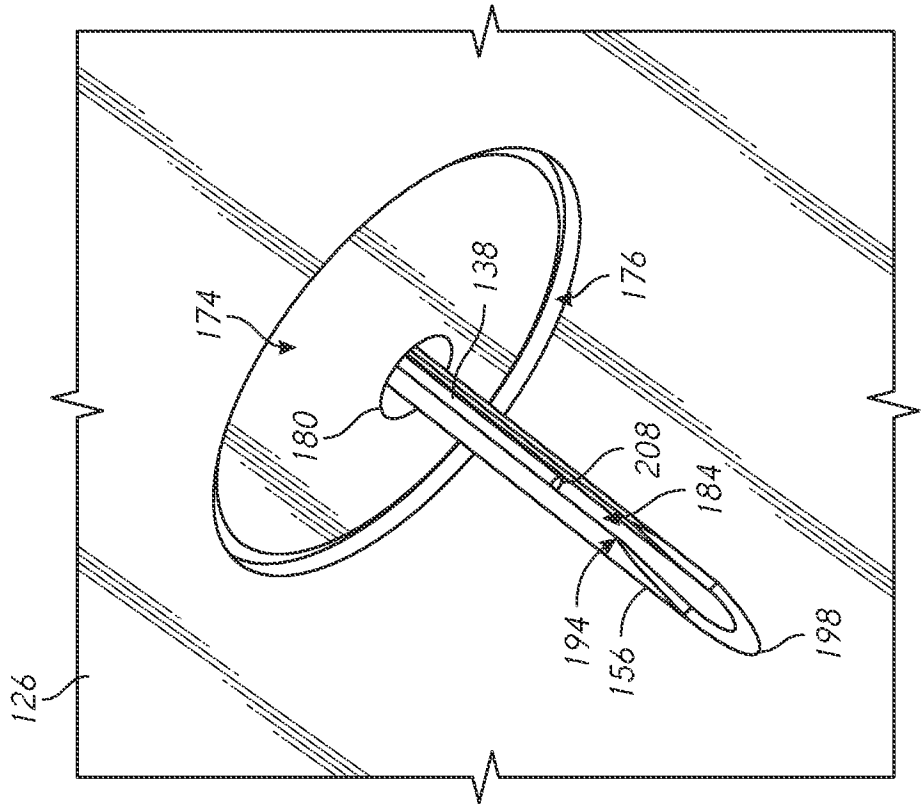

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FIG. 13

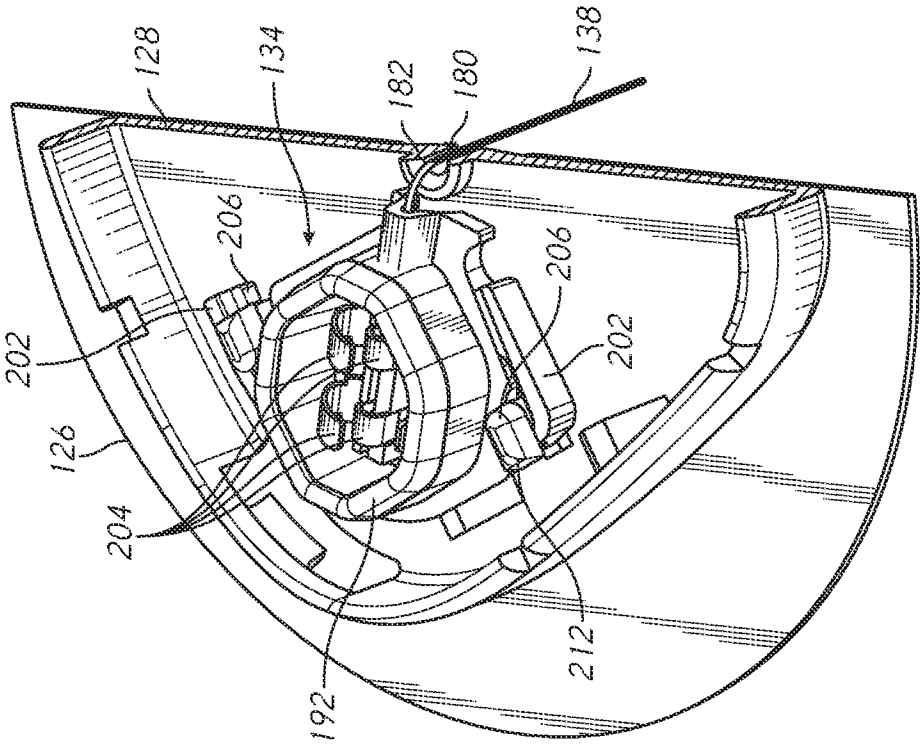

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FIG. 16

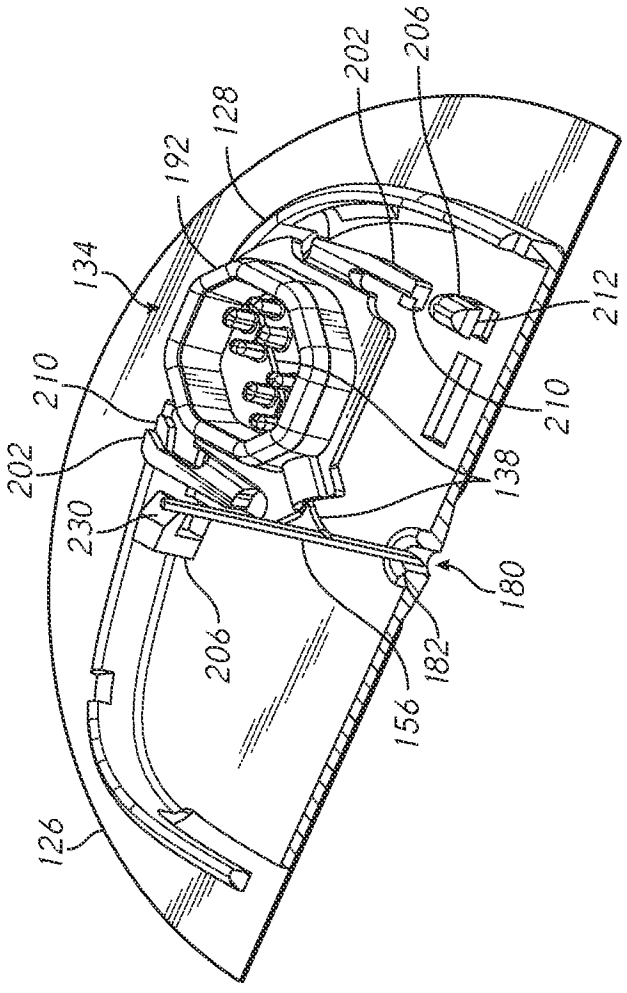

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FIG. 15

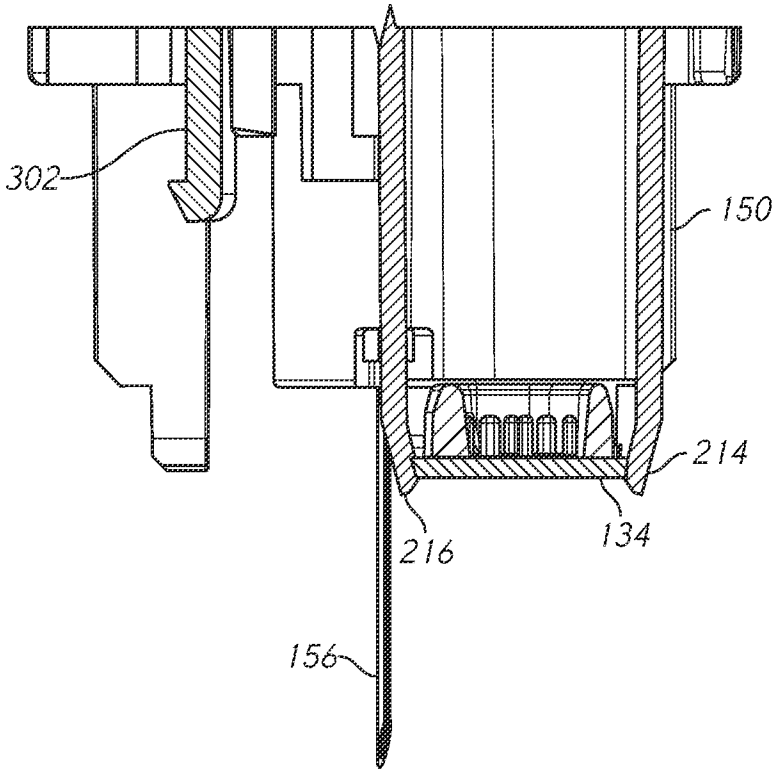

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FIG. 17

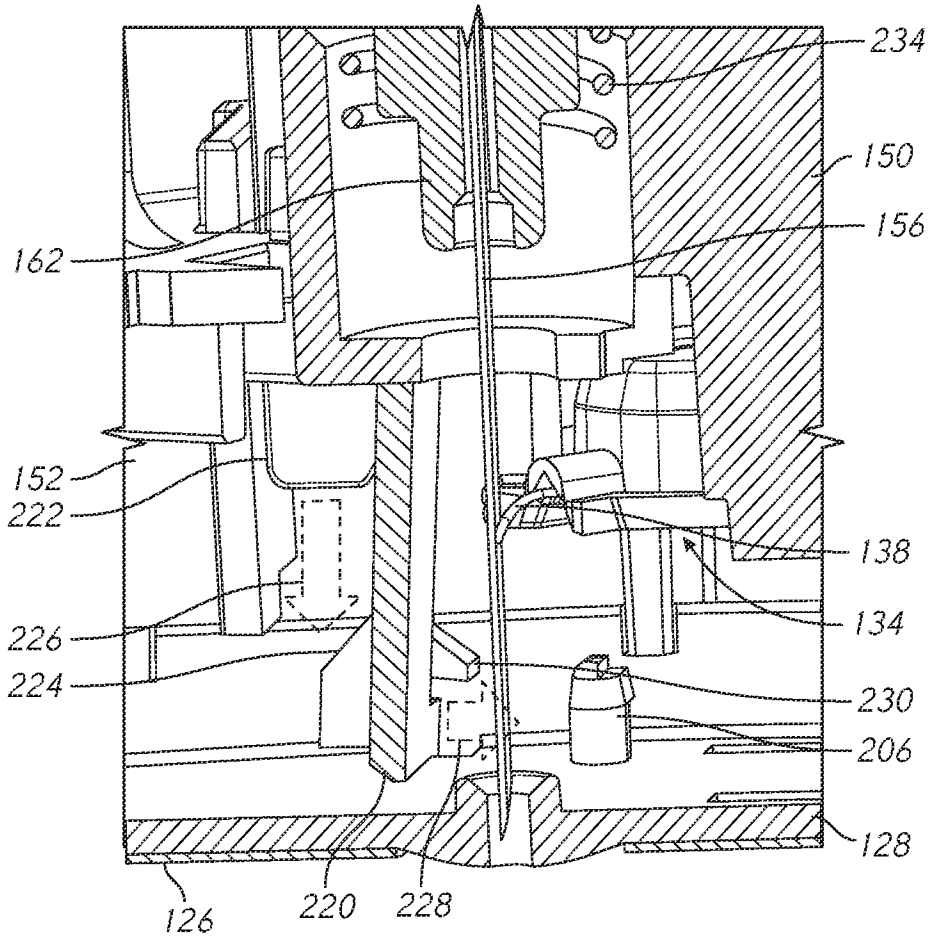

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FIG. 18

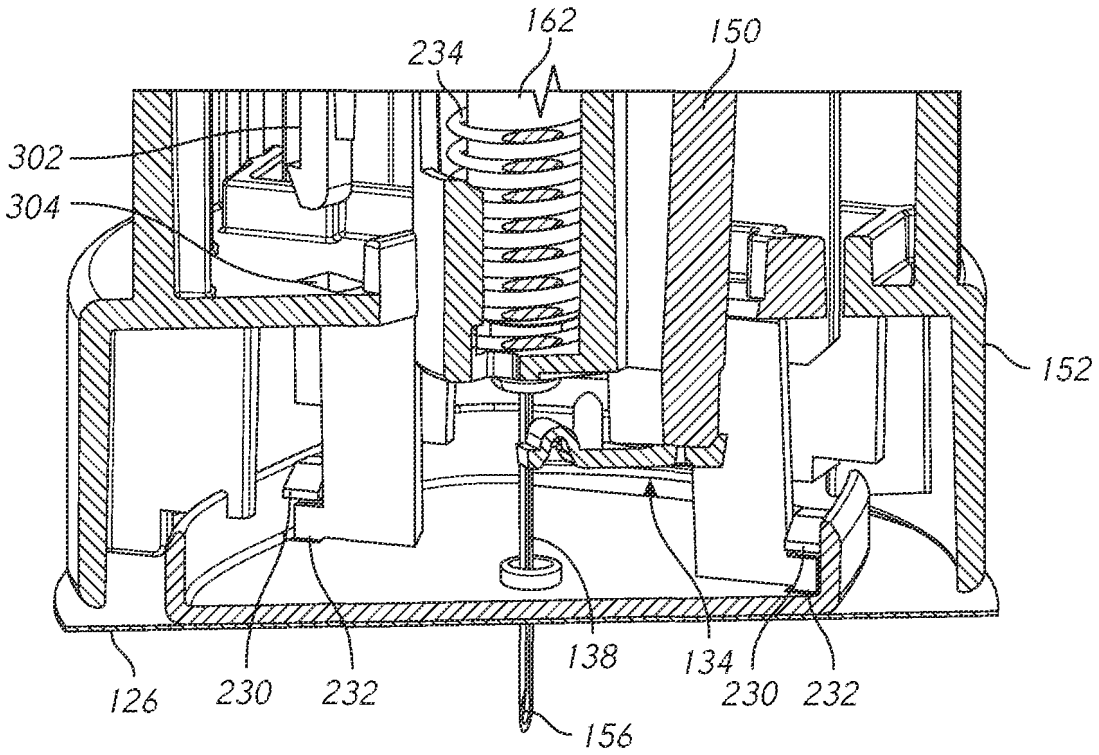

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FIG. 19

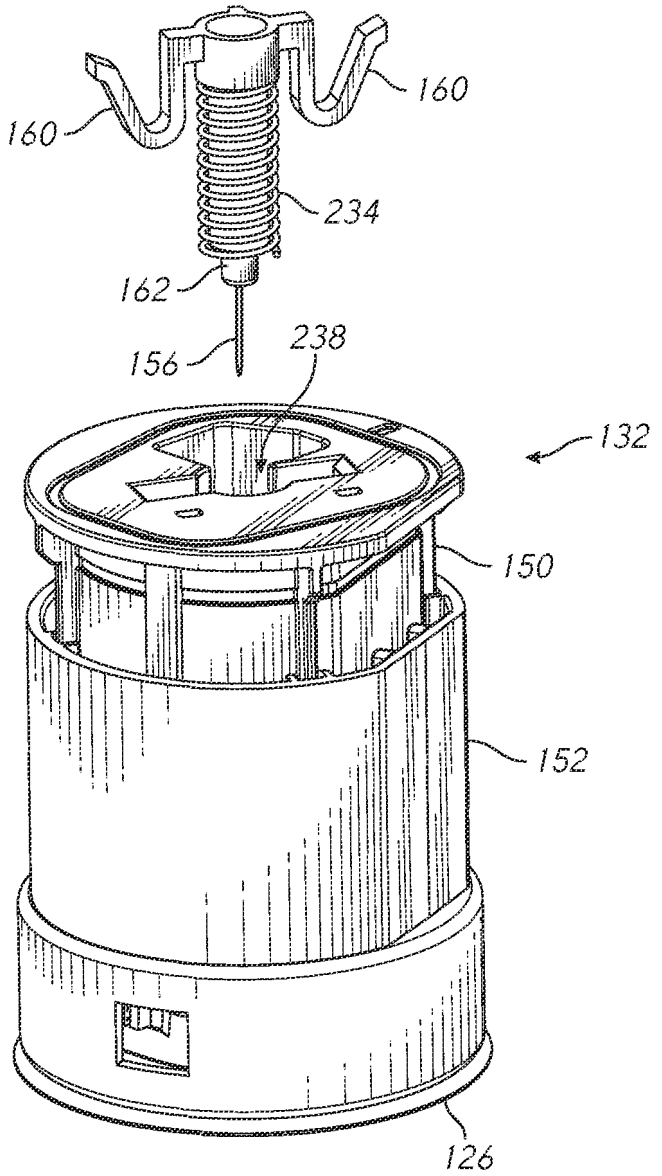

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FIG. 20

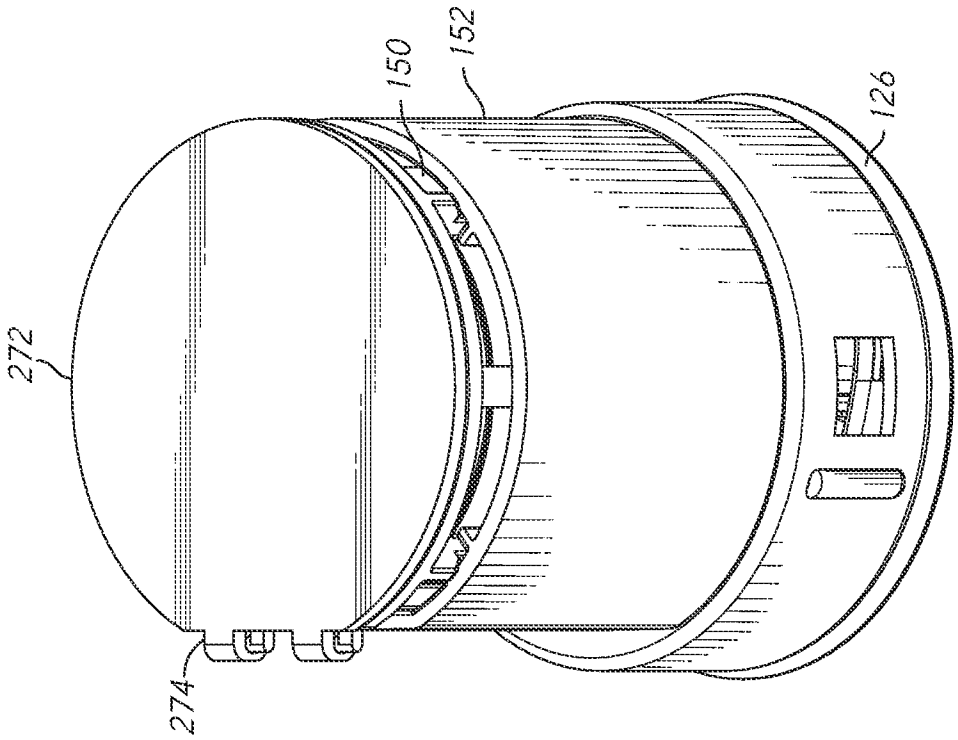

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FIG. 22

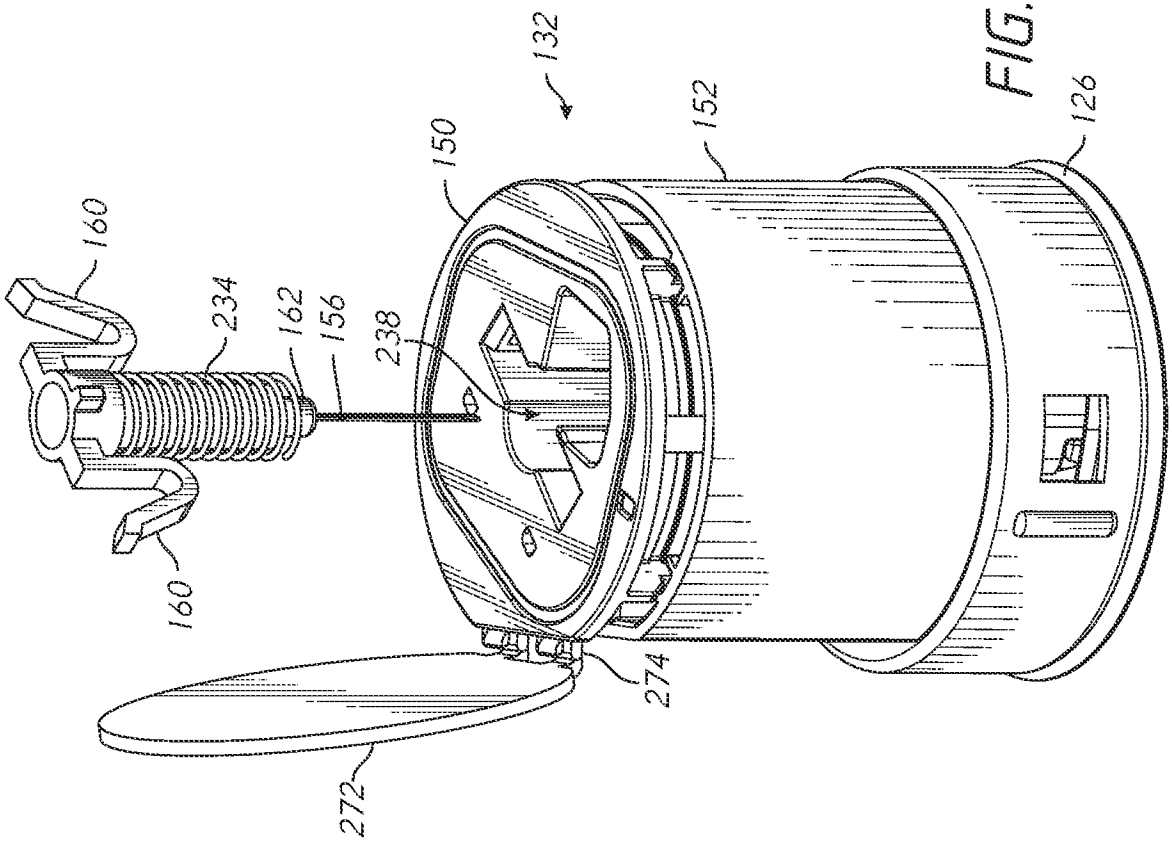

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FIG. 21

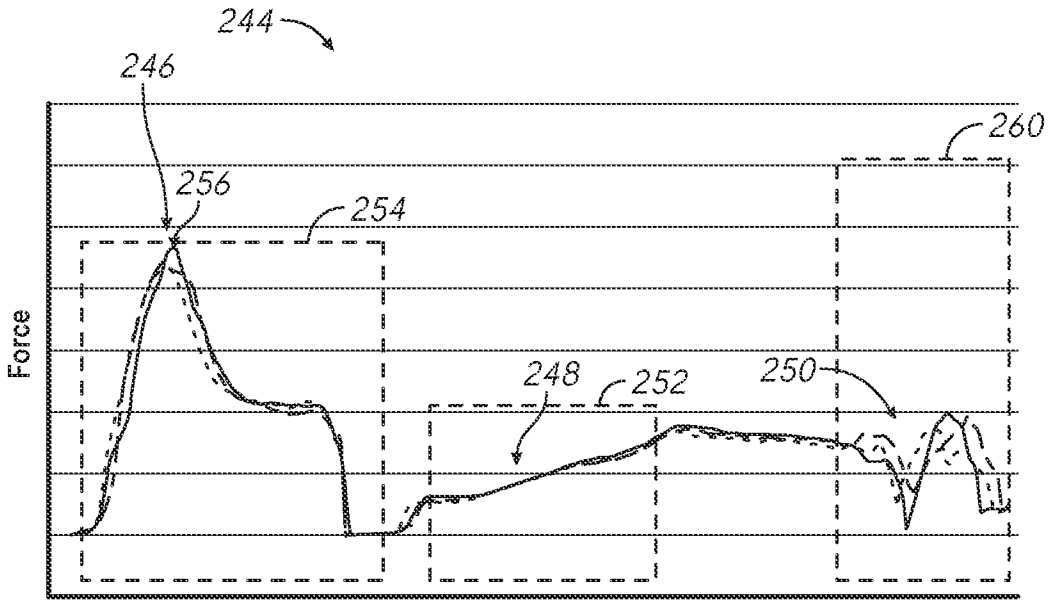

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Travel

FIG. 23

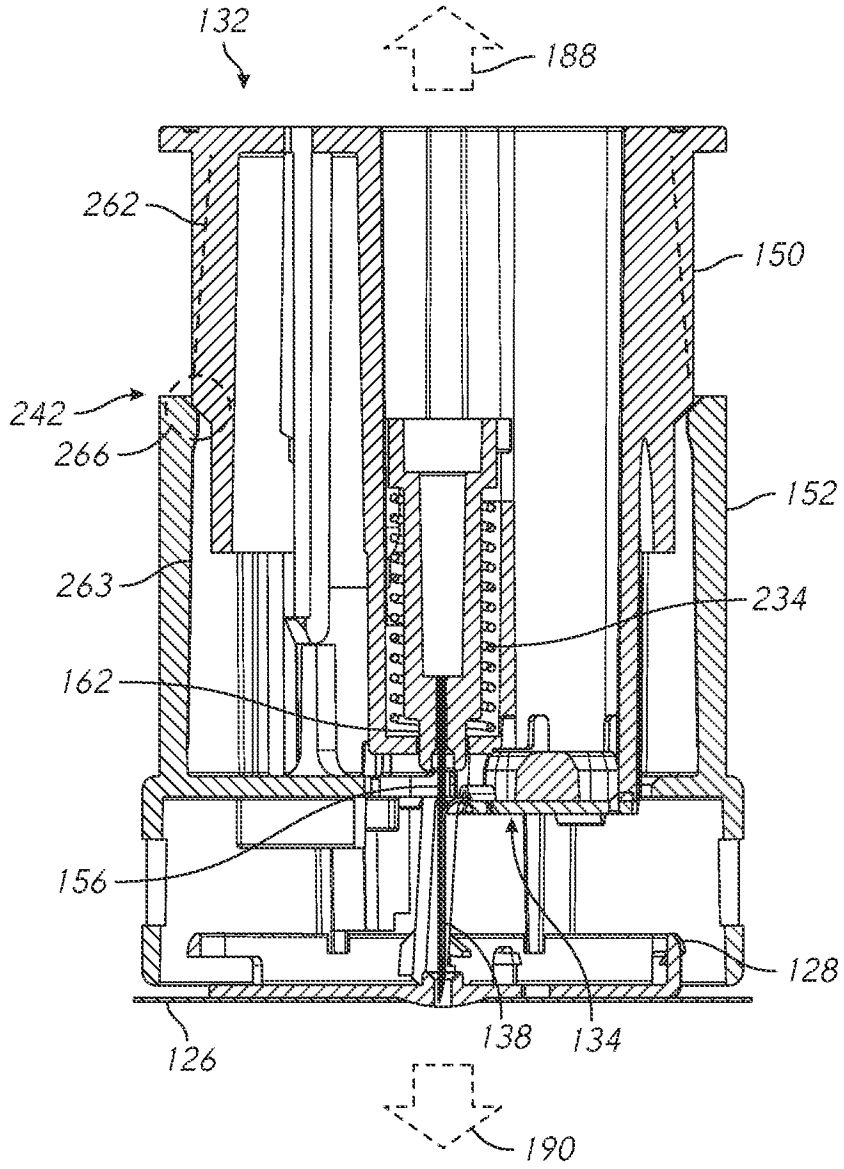

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FIG. 24

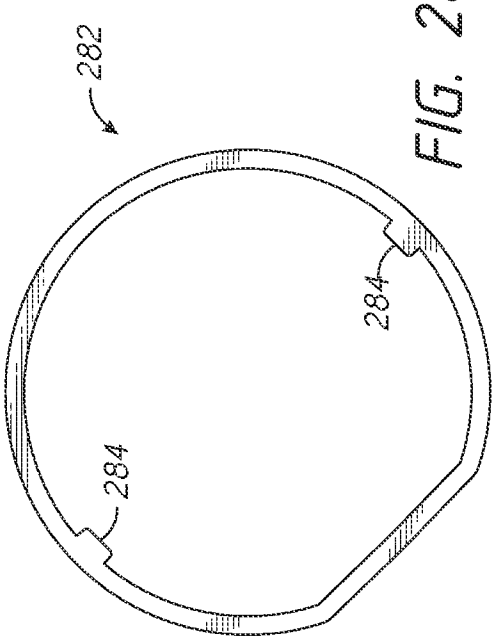


FIG. 26

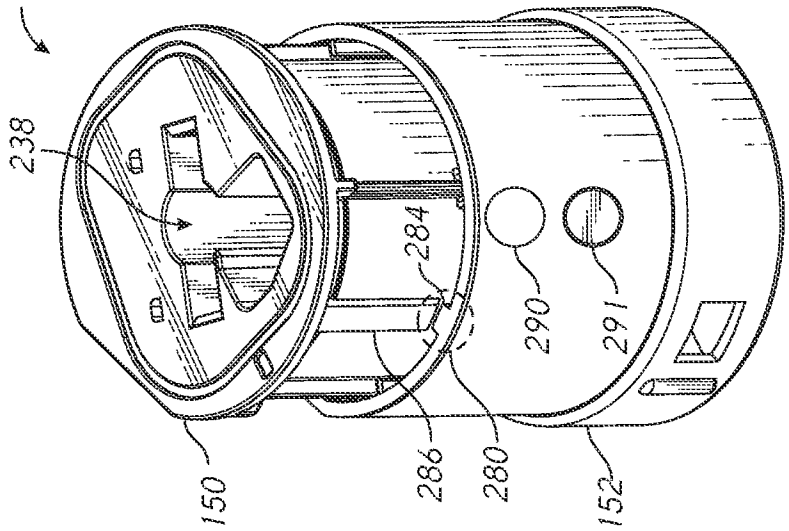


FIG. 27

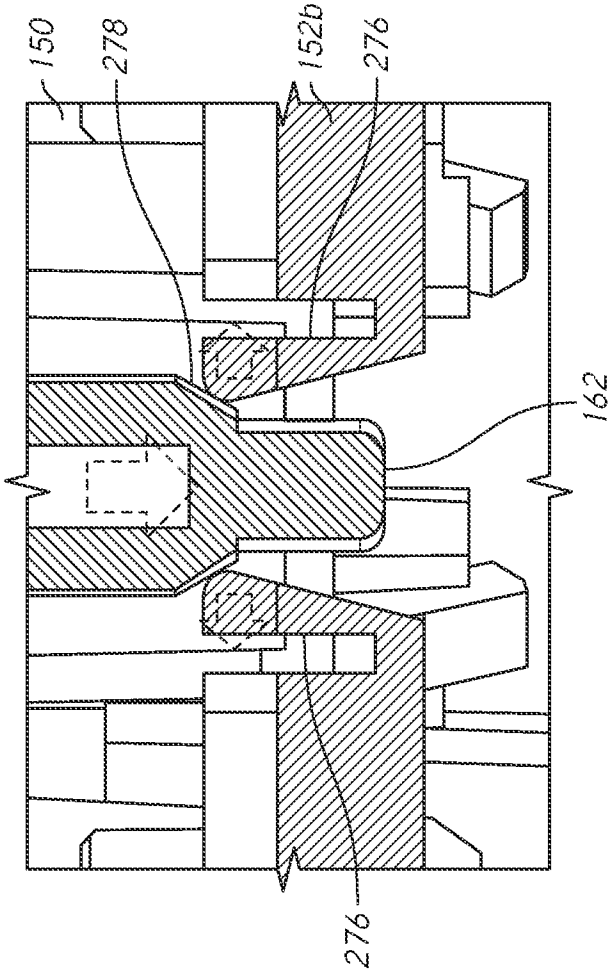


FIG. 25

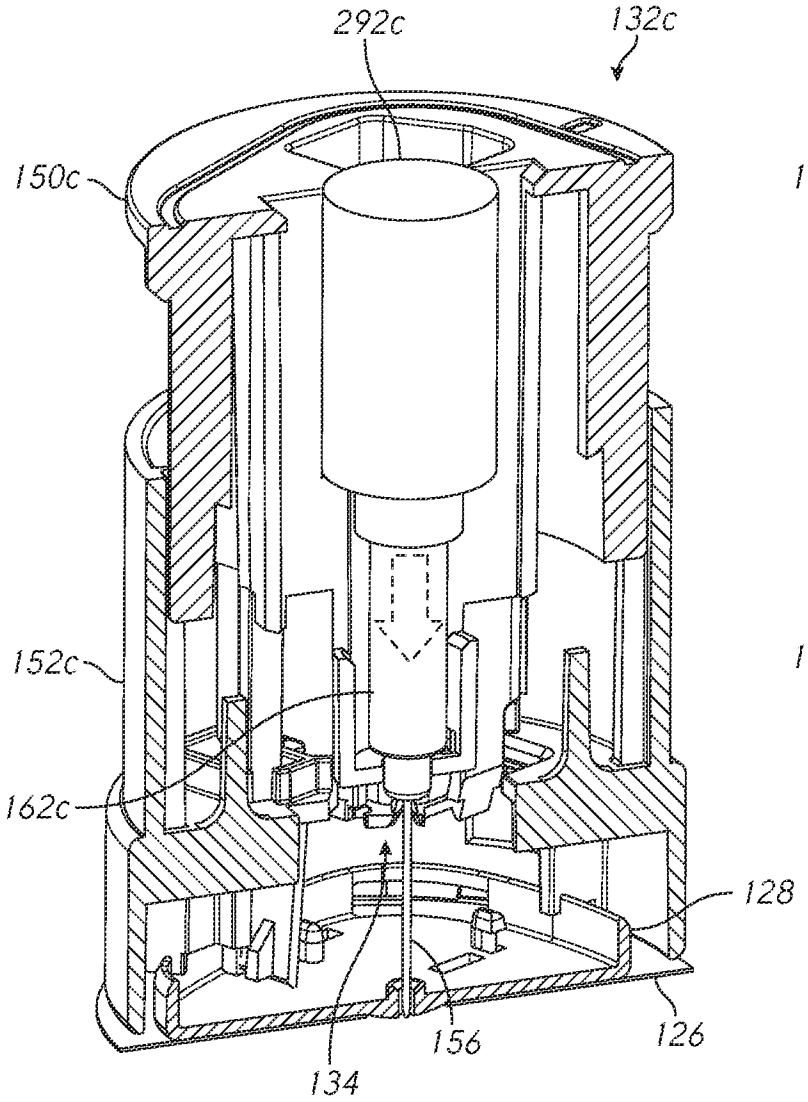

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FIG. 28

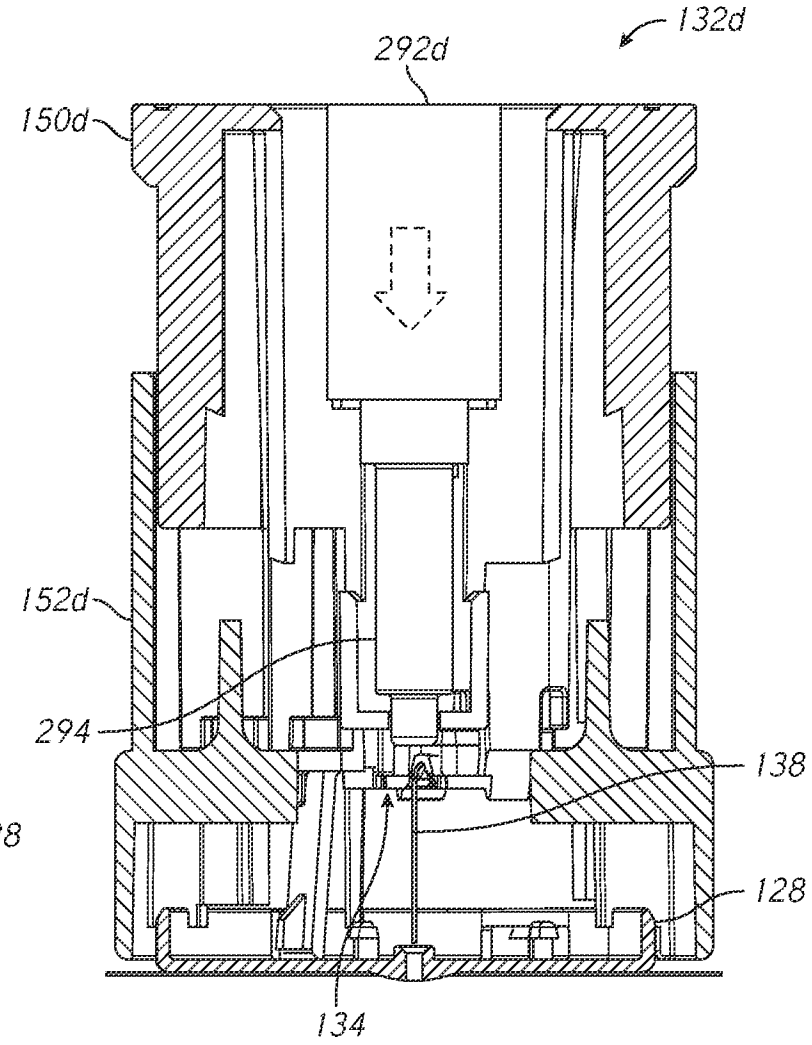

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FIG. 29

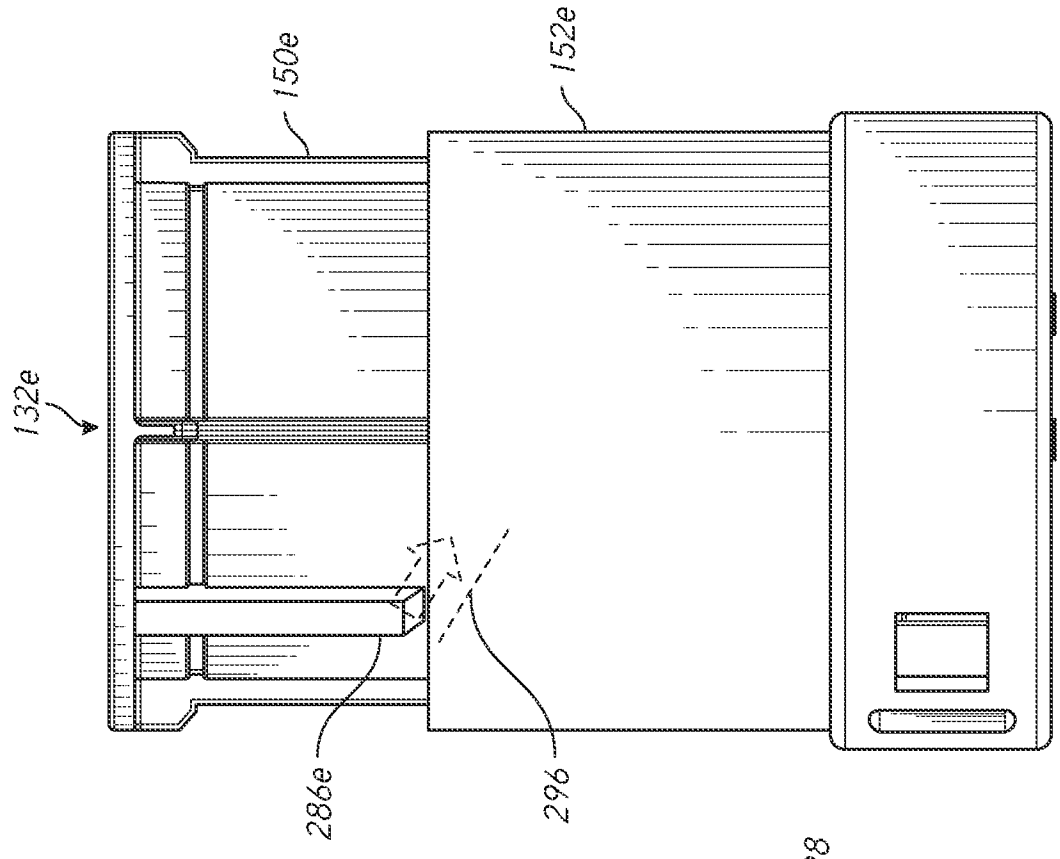


FIG. 31

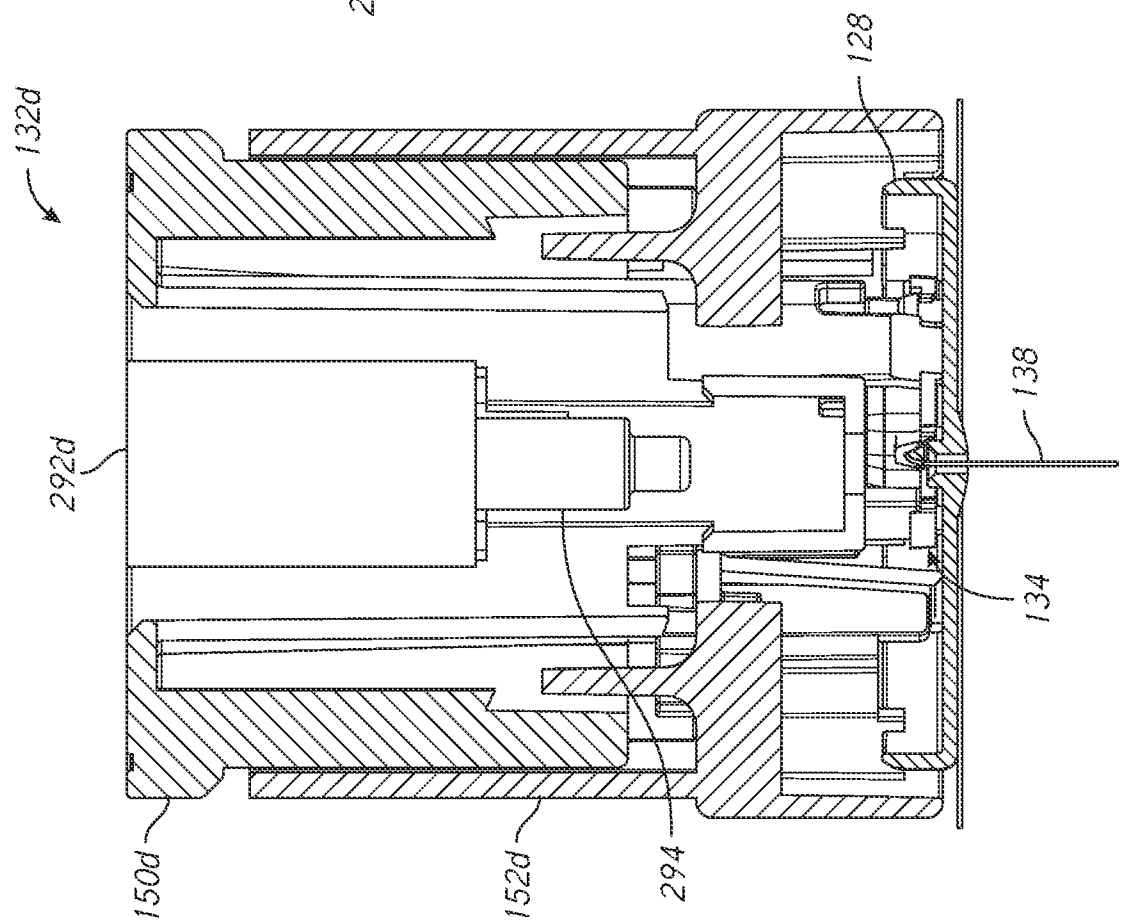


FIG. 30

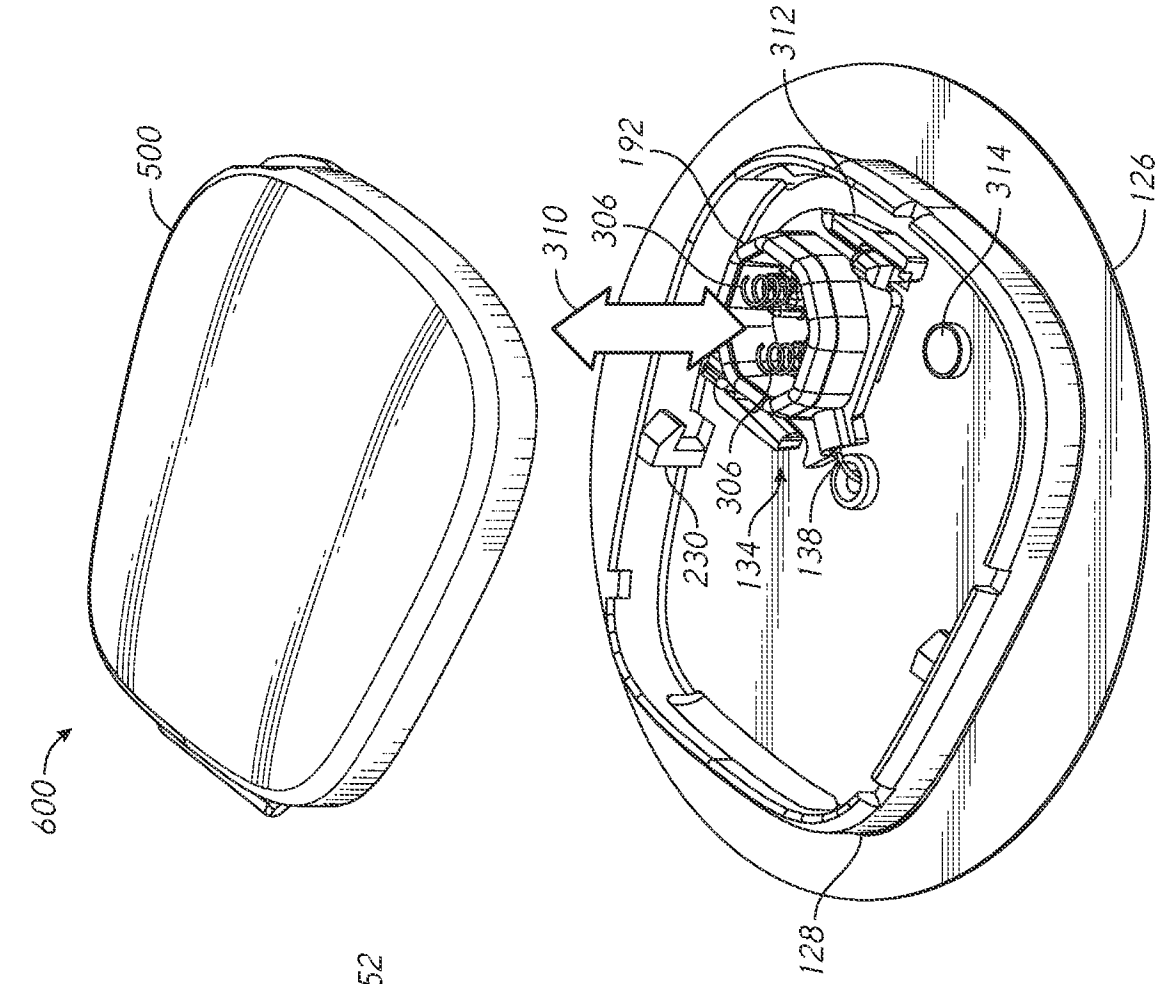

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FIG. 33

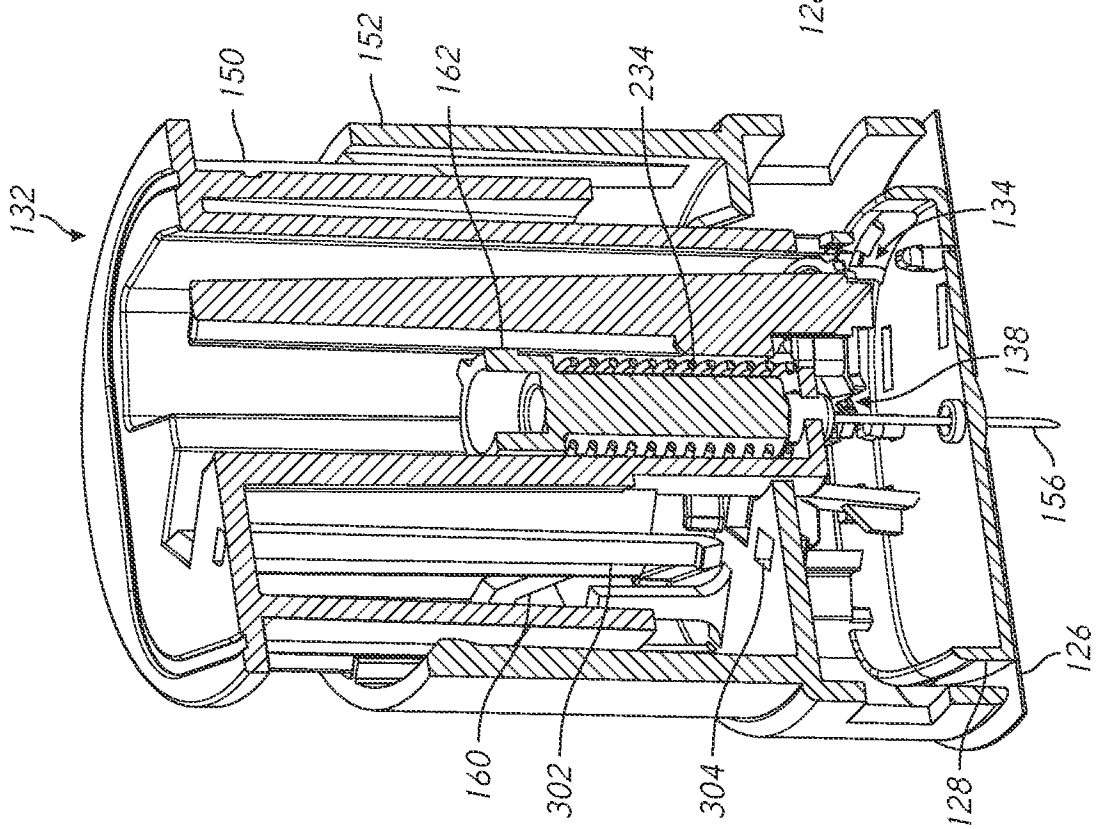

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FIG. 32

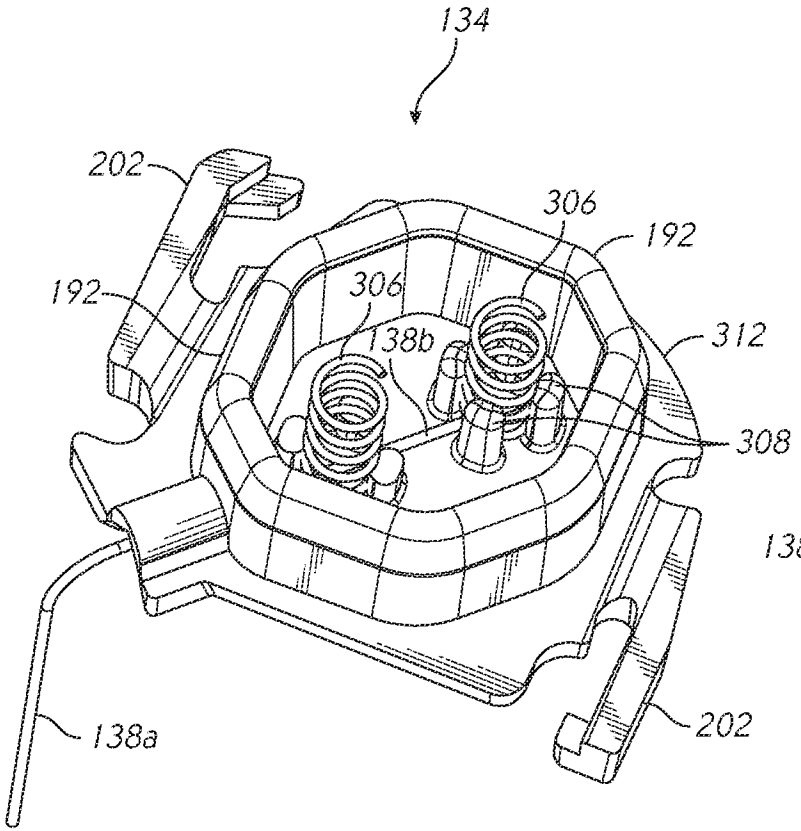


FIG. 34

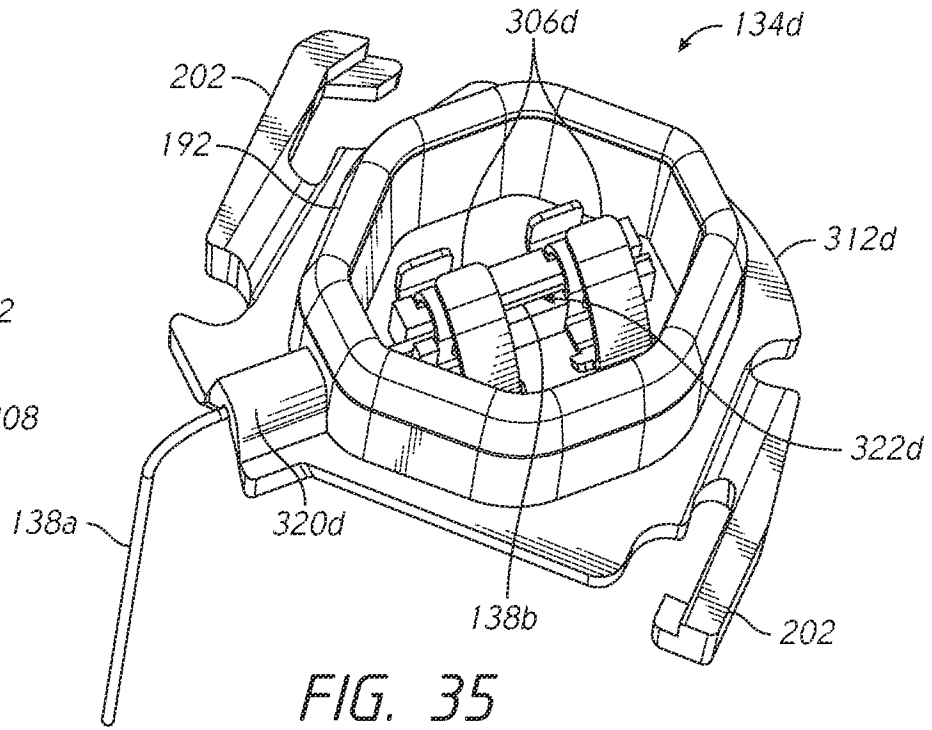


FIG. 35

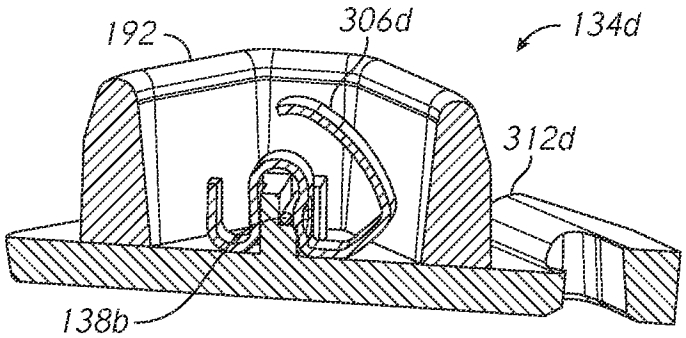


FIG. 36

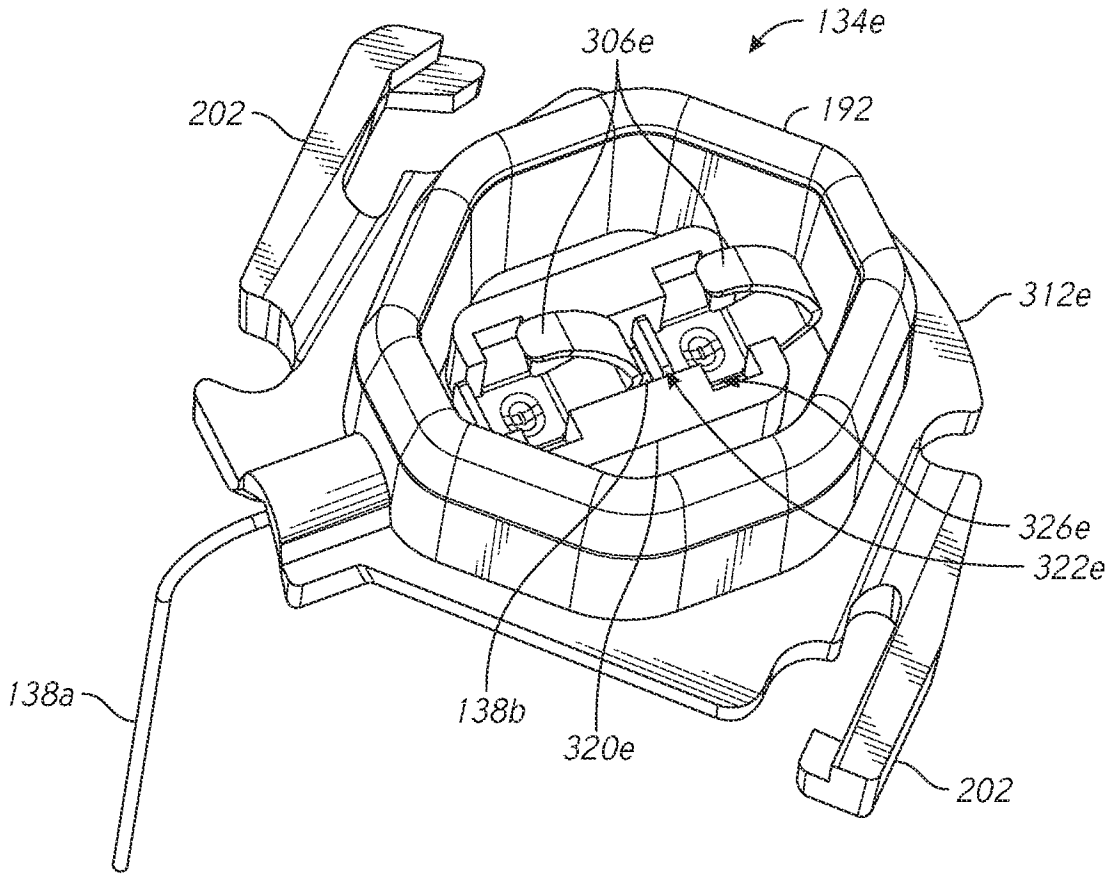

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202

FIG. 37

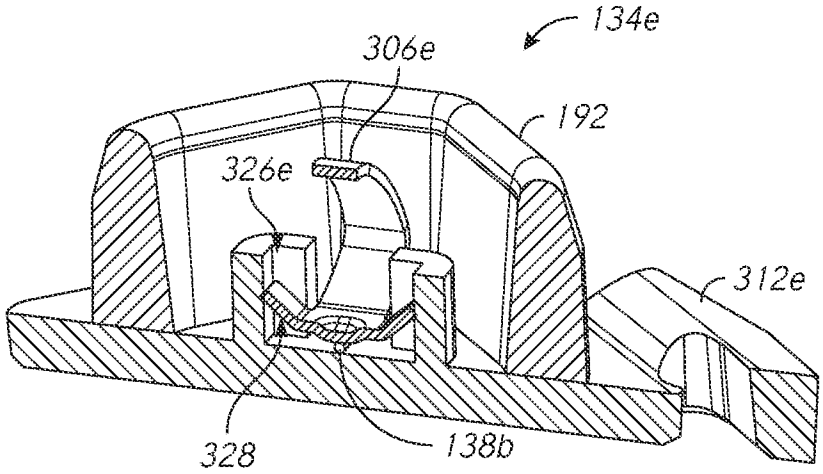

134e
306e
192
326e
312e
328
138b

FIG. 38

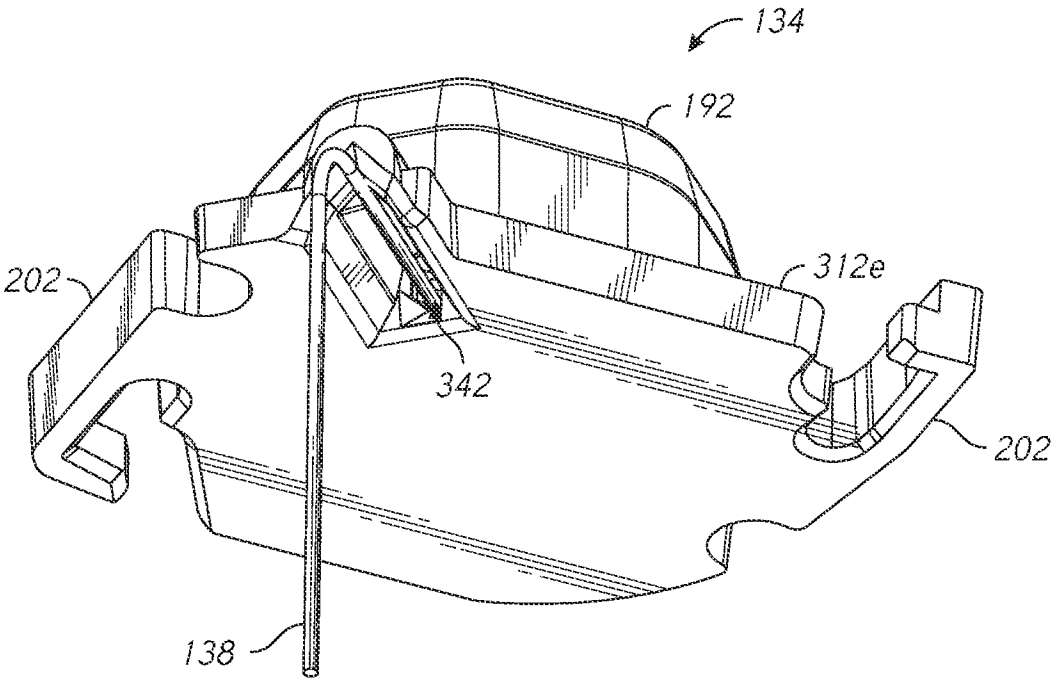

134
192
202
312e
342
202
138

FIG. 39

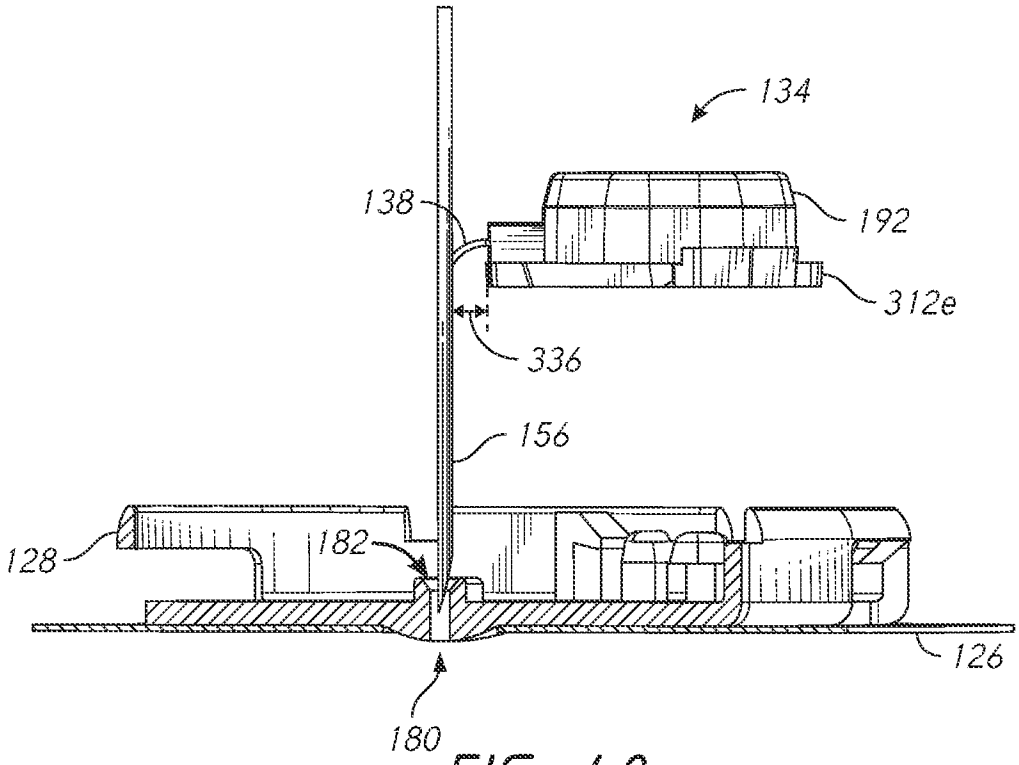

134
138
192
312e
336
156
128
182
126
180

FIG. 40

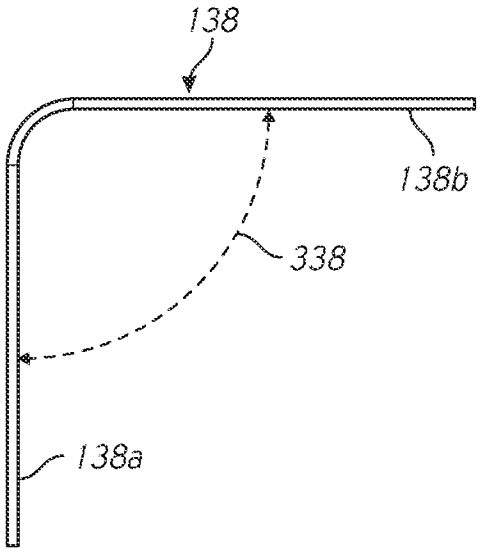
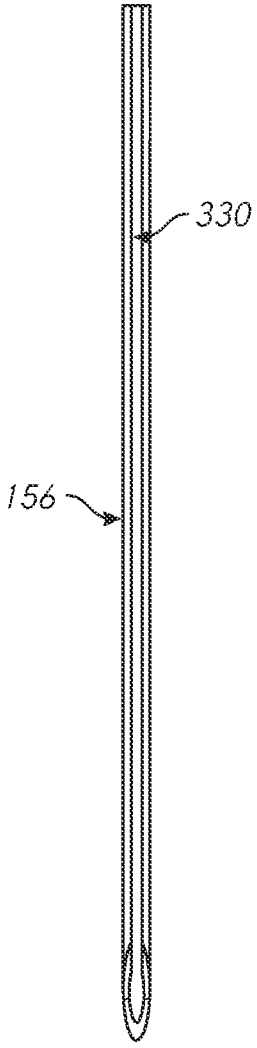


FIG. 41



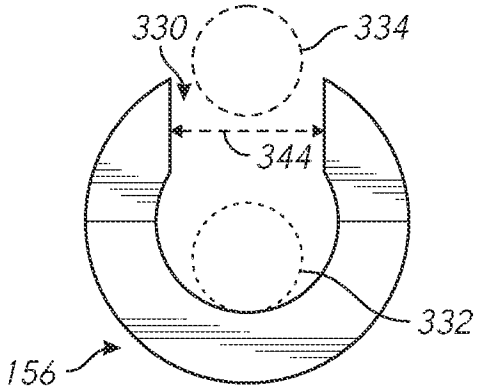


FIG. 42

FIG. 43

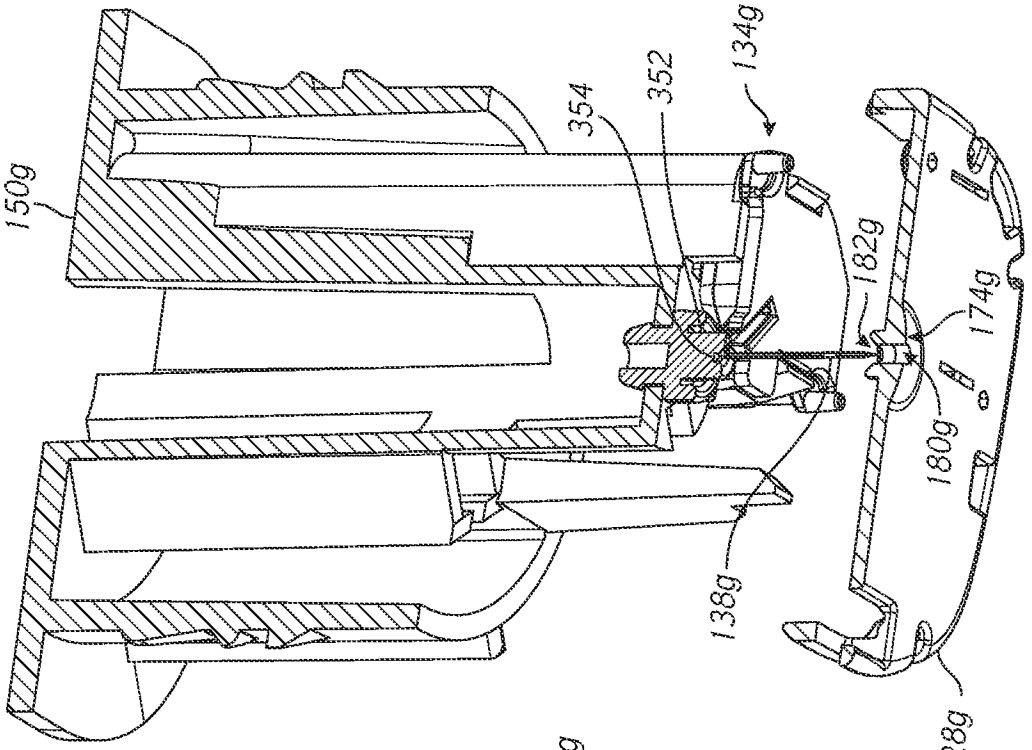

150g
354
352
134g
182g
174g
180g
138g
128g

FIG. 45

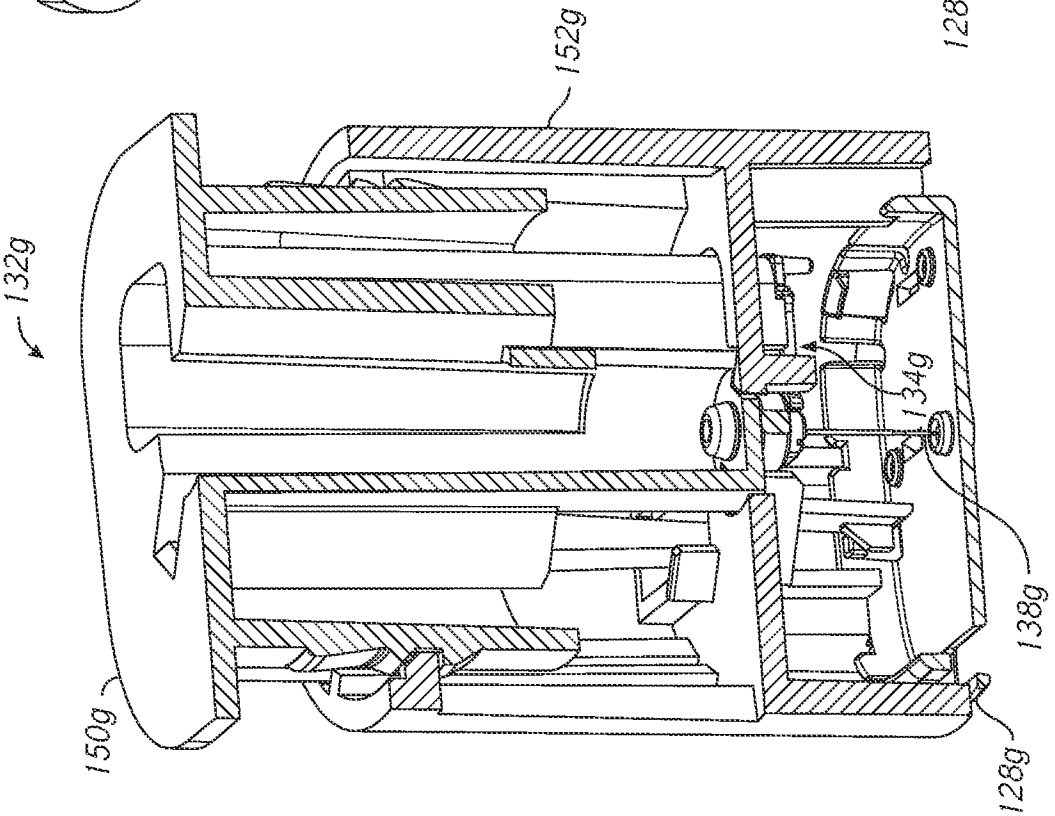

152g
132g
134g
138g
150g
128g

FIG. 44

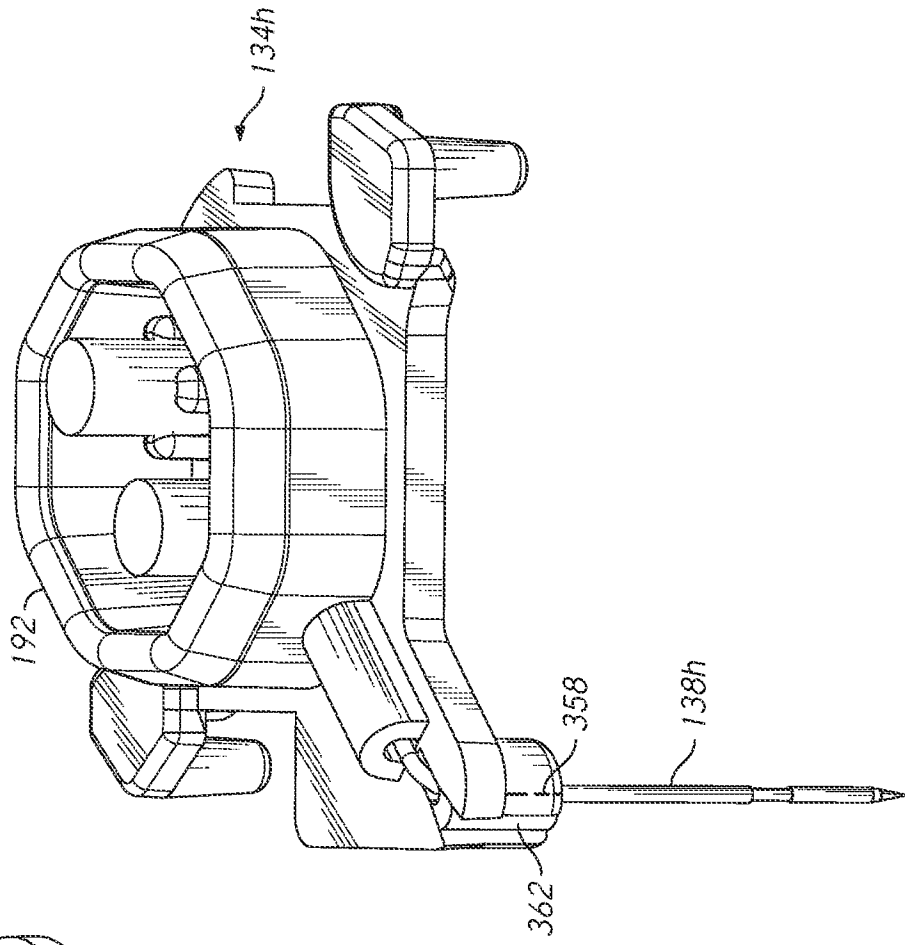


FIG. 47

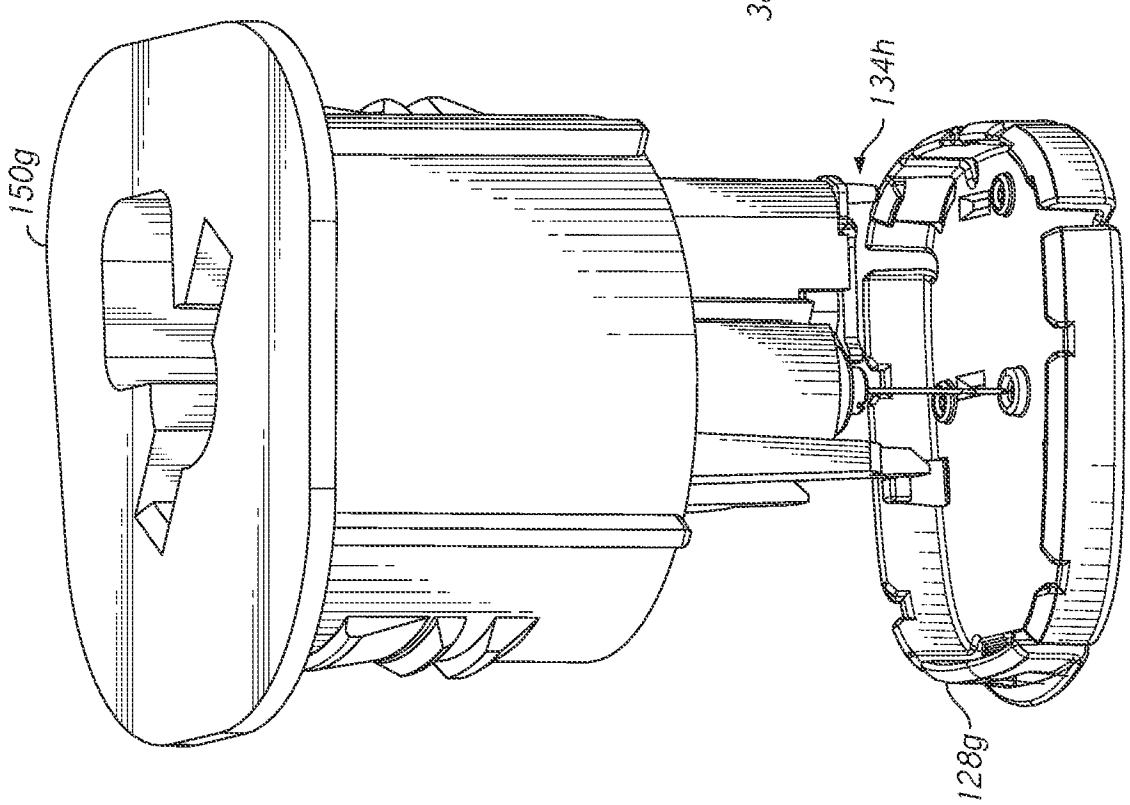


FIG. 46

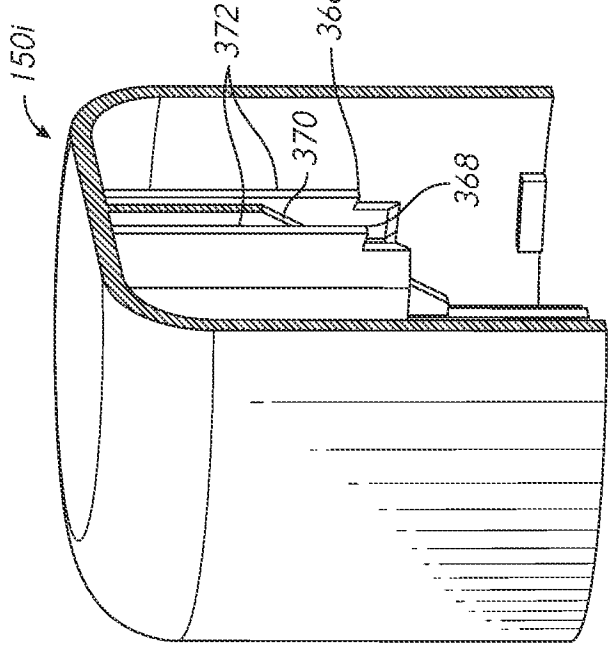


FIG. 49

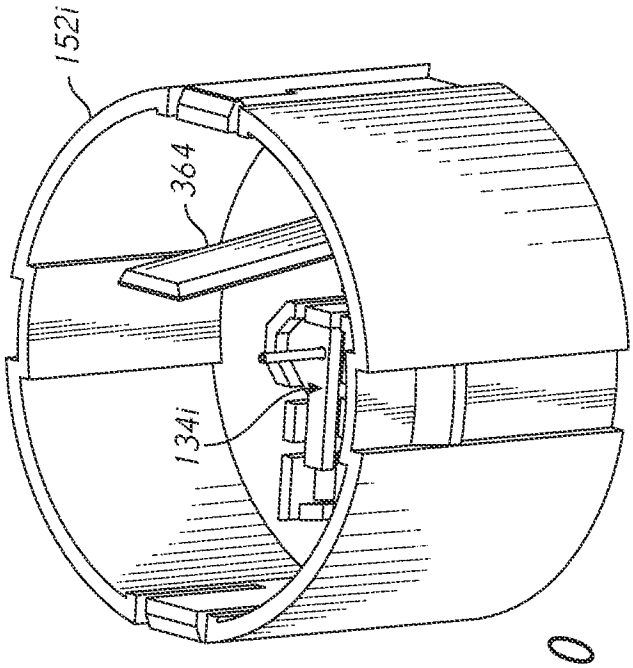


FIG. 50

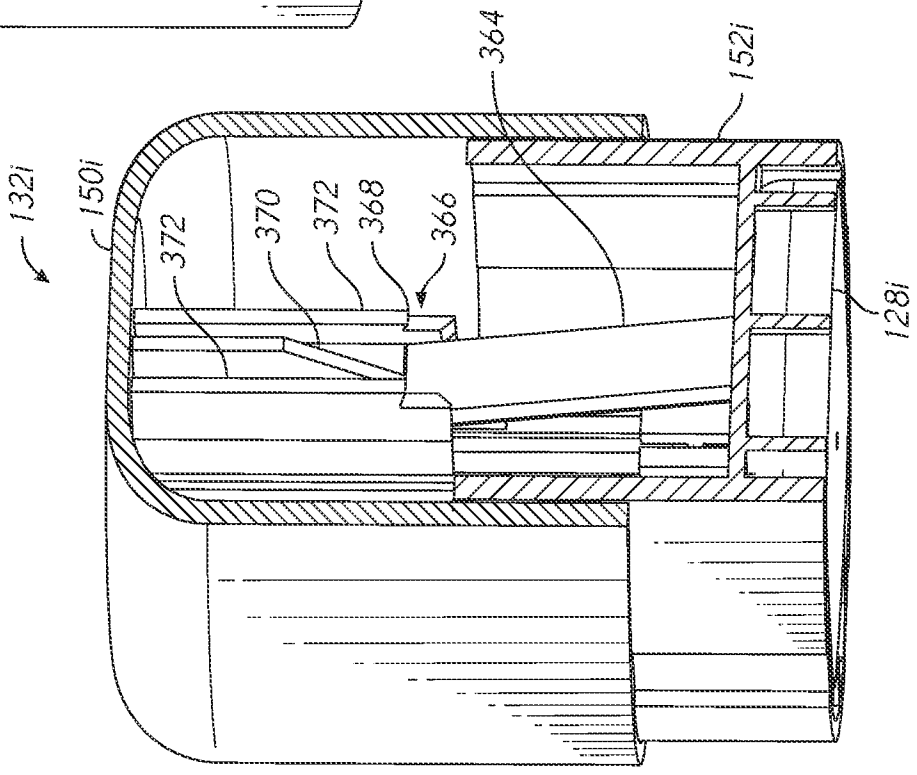


FIG. 48

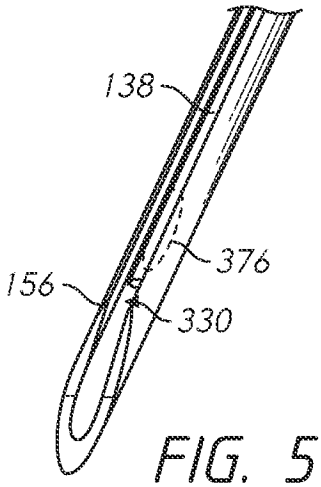


FIG. 51

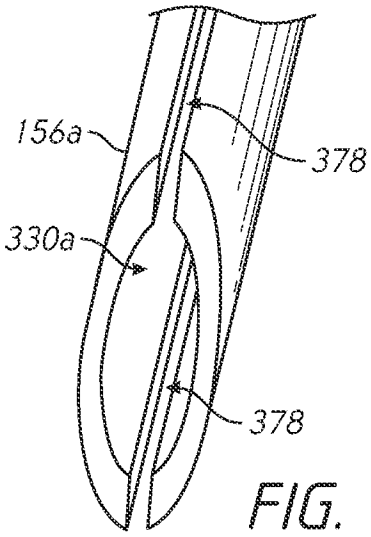


FIG. 52

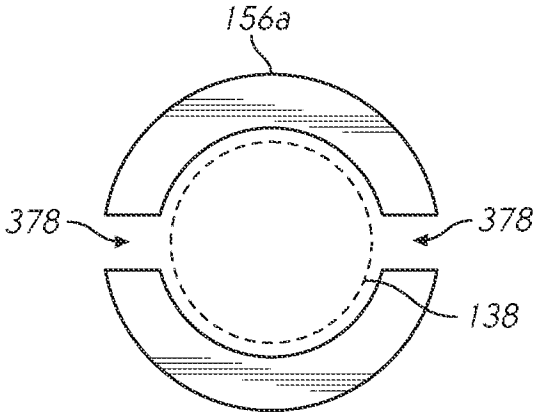


FIG. 53

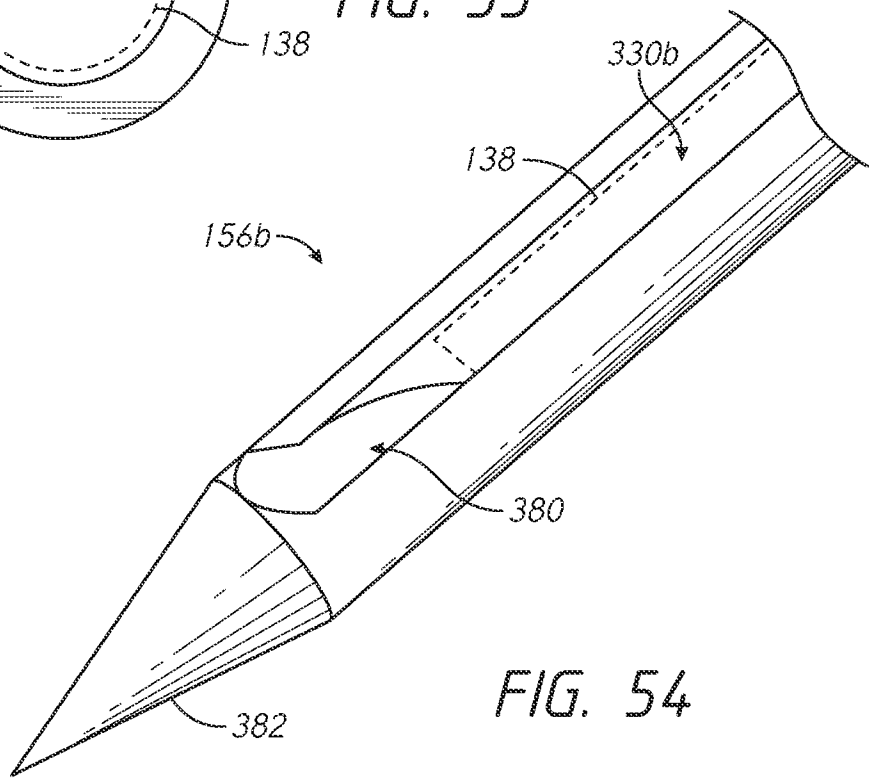


FIG. 54

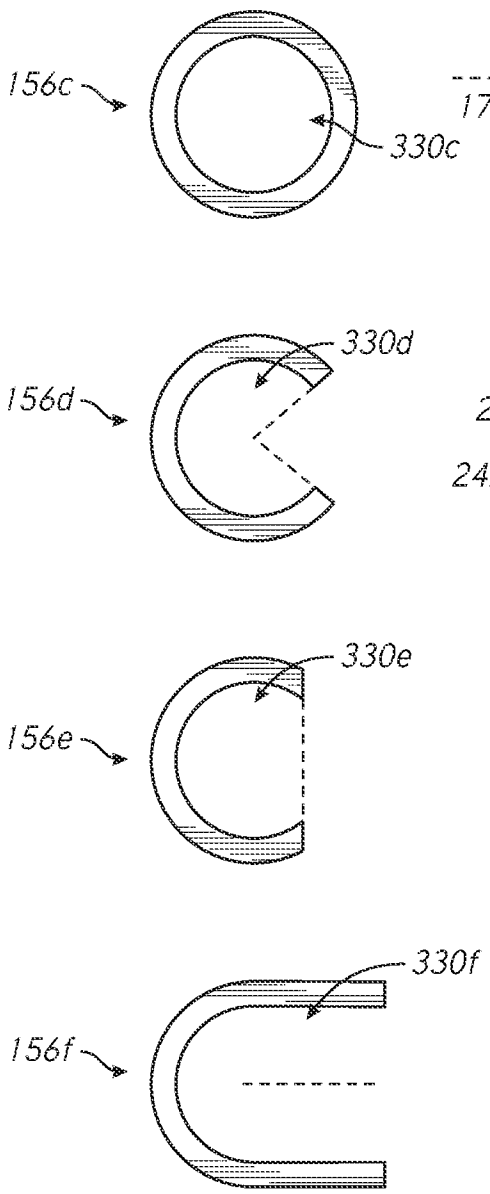

156c
330c
330d
156d
330e
156e
330f
156f

FIG. 55

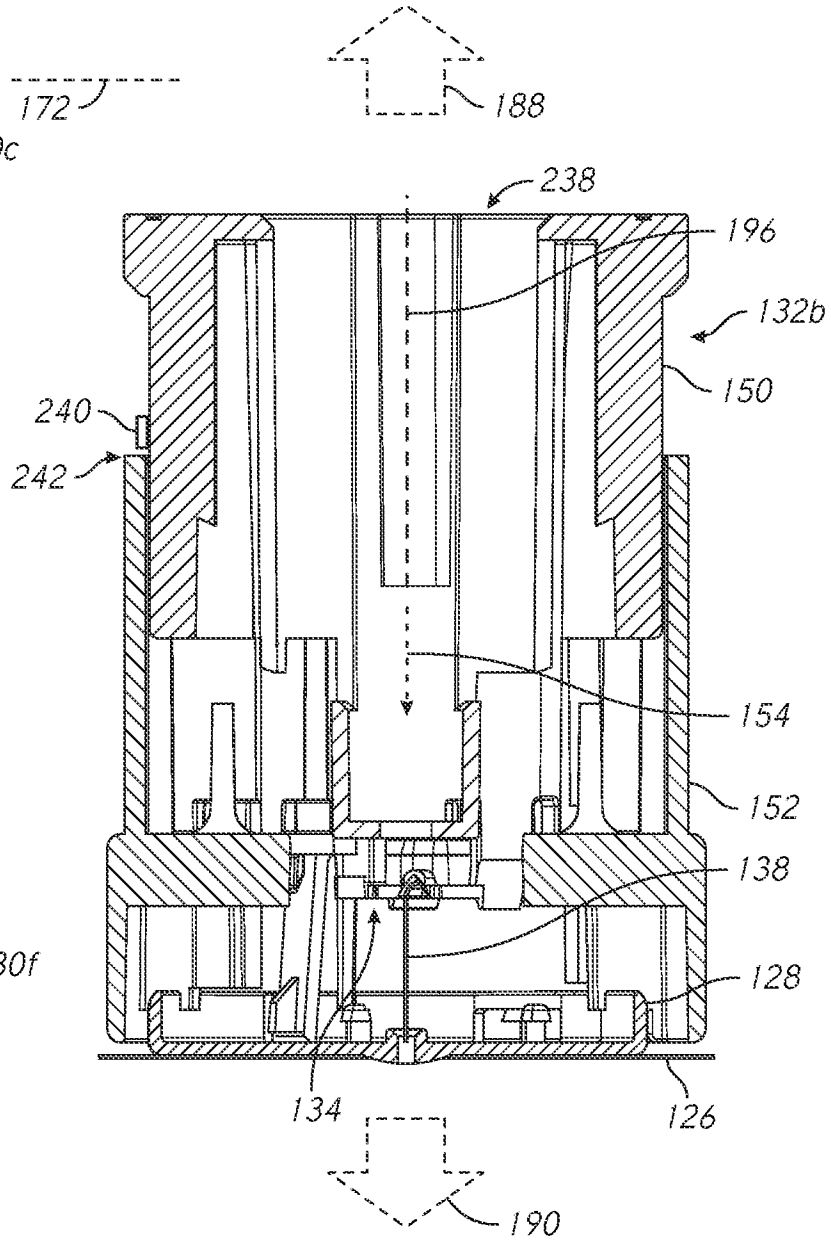

172
188
238
196
132b
150
240
242
154
152
138
128
134
126
190

FIG. 56

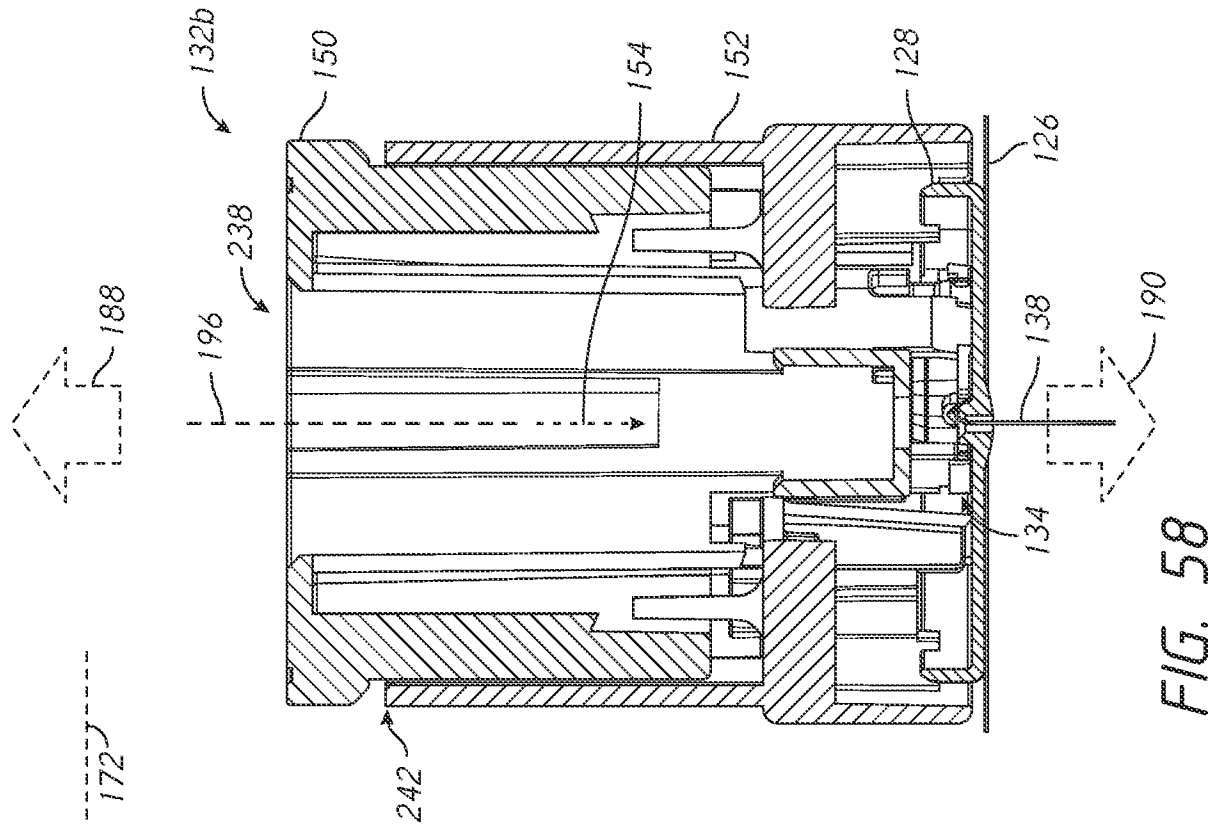

132b
150
154
152
128
126
238
196
188
138
190
134
172
242

FIG. 58

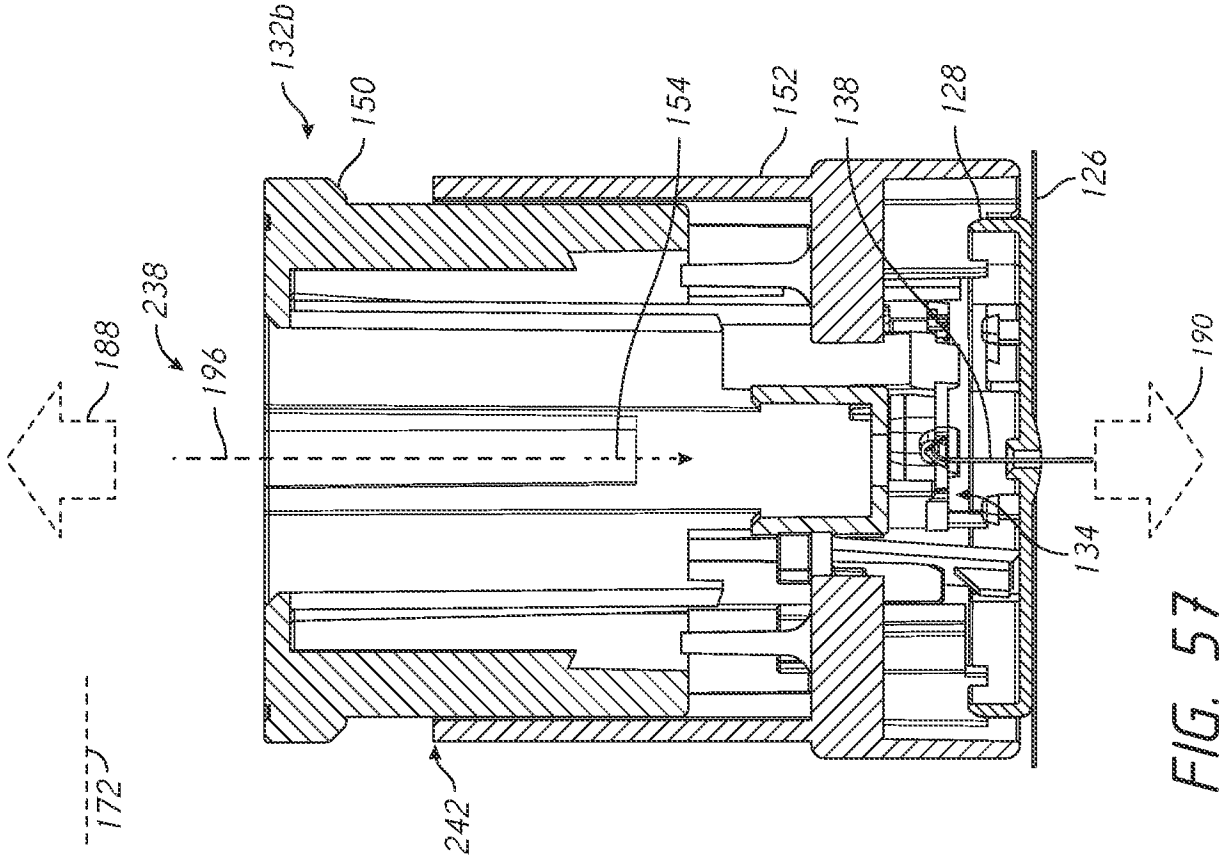

132b
150
154
152
138
128
126
238
196
188
190
134
172
242

FIG. 57

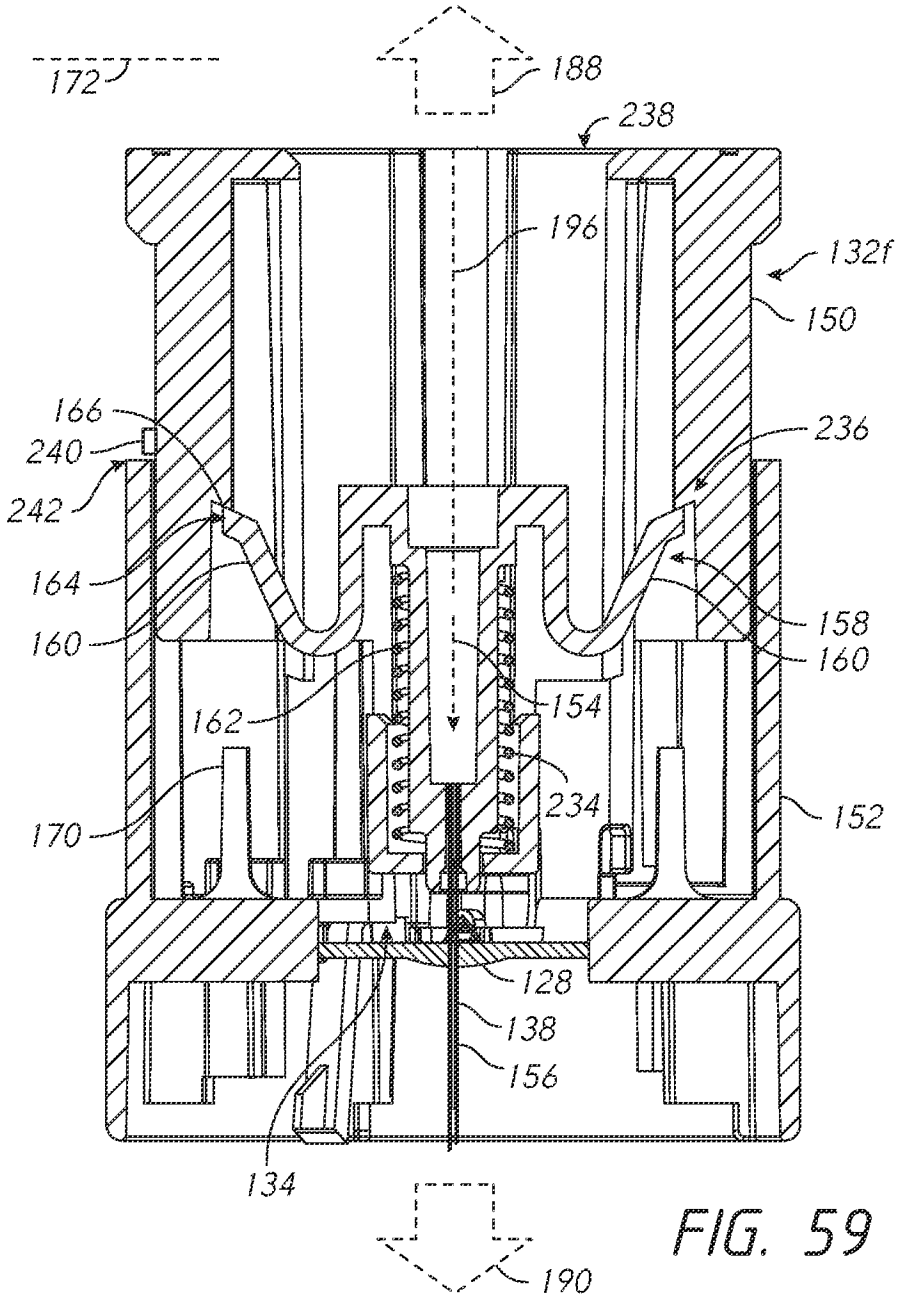

172
188
238
196
132f
150
166
240
242
236
164
160
158
160
162
154
234
170
152
128
138
156
134
190

FIG. 59

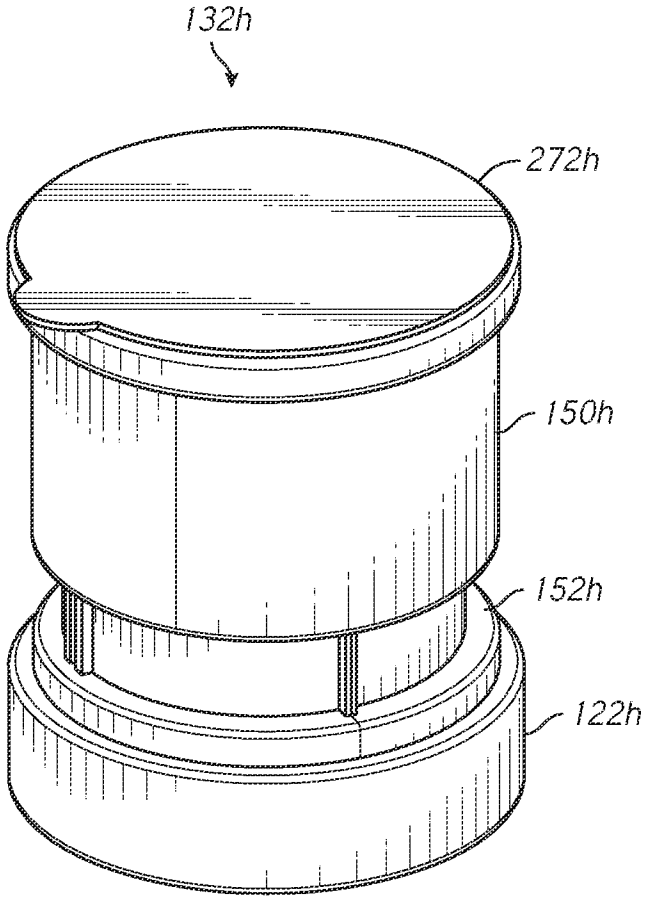

132h
272h
150h
152h
122h

FIG. 60

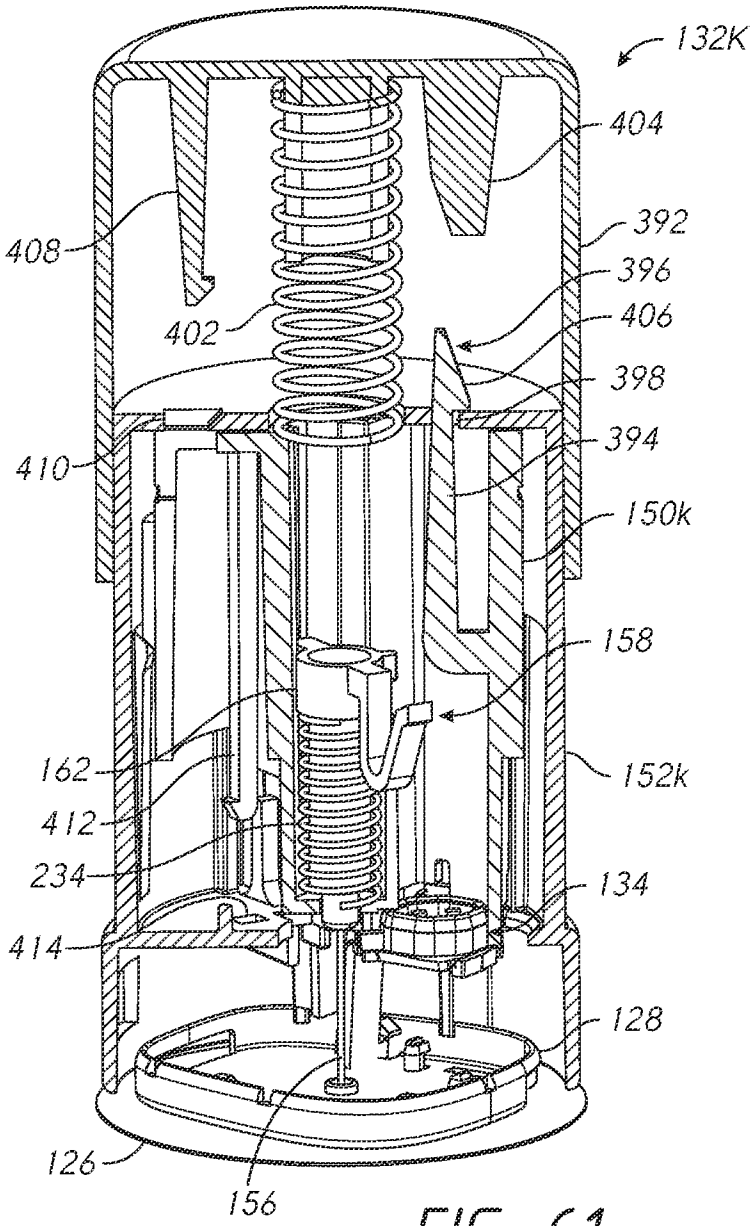

132K
404
408
392
396
402
406
398
410
394
150k
158
162
152k
412
234
134
414
128
126
156

FIG. 61

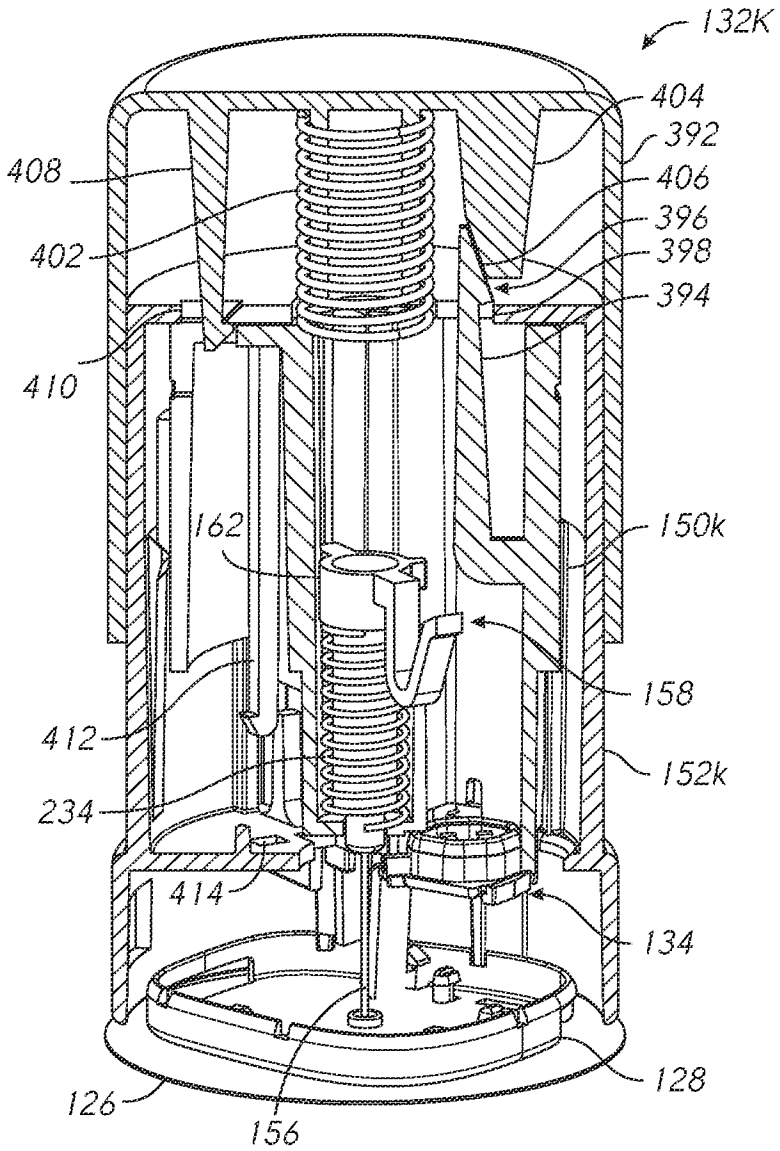

132K
404
392
408
406
396
402
398
394
410
150k
162
158
412
152k
234
414
134
128
126
156

FIG. 62

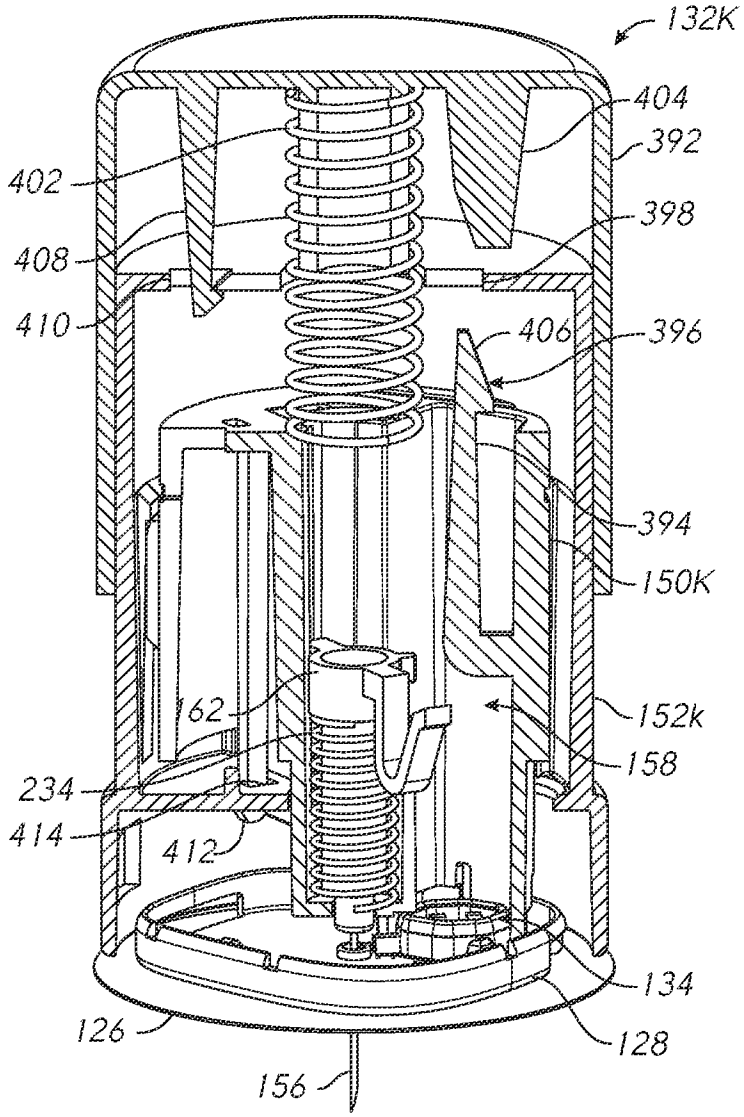

132K
404
392
402
398
408
410
406
396
394
150K
162
152k
158
234
414
412
134
126
128
156

FIG. 63

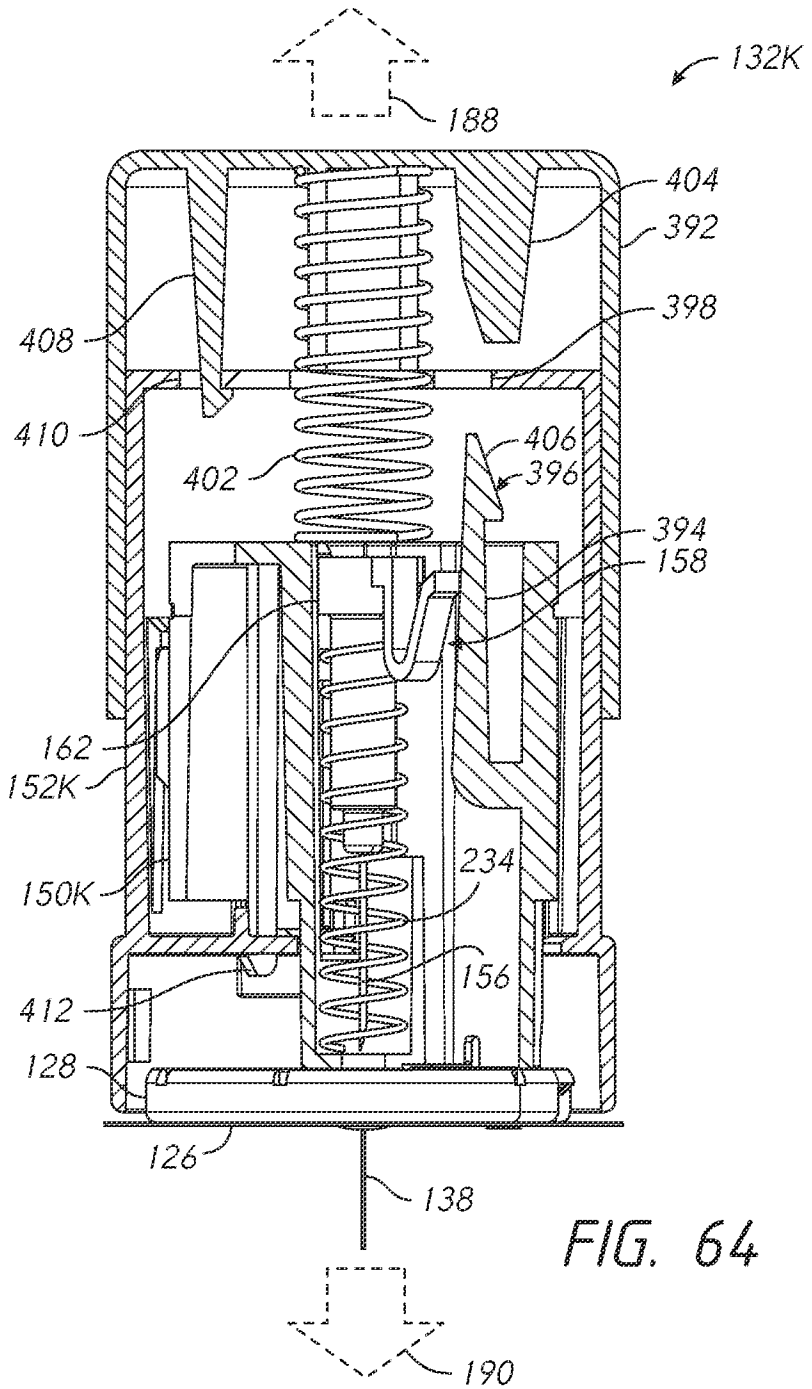

132K
188
404
392
408
398
410
406
396
402
394
158
162
152K
150K
234
156
412
128
126
138
190

FIG. 64

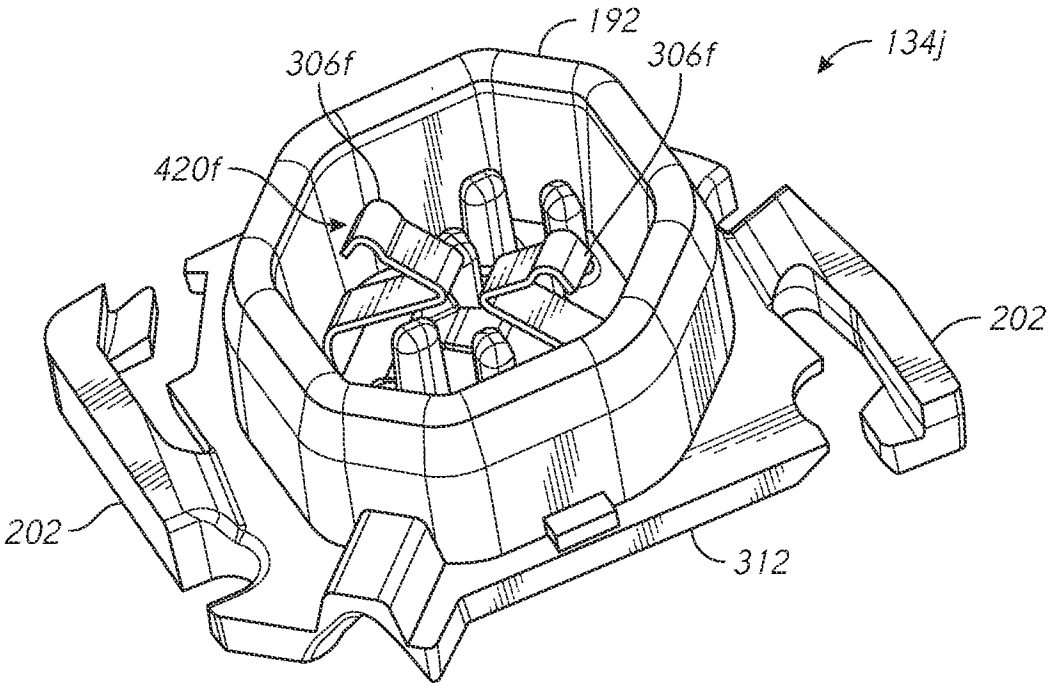

192
306f
306f
134j
420f
202
202
312

FIG. 65

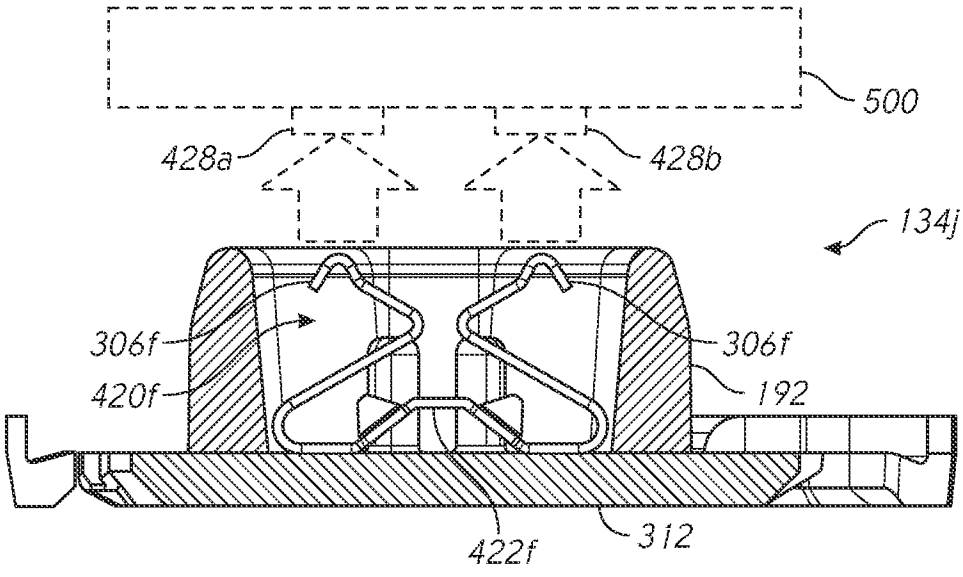

500
428a
428b
134j
306f
306f
420f
192
422f
312

FIG. 66

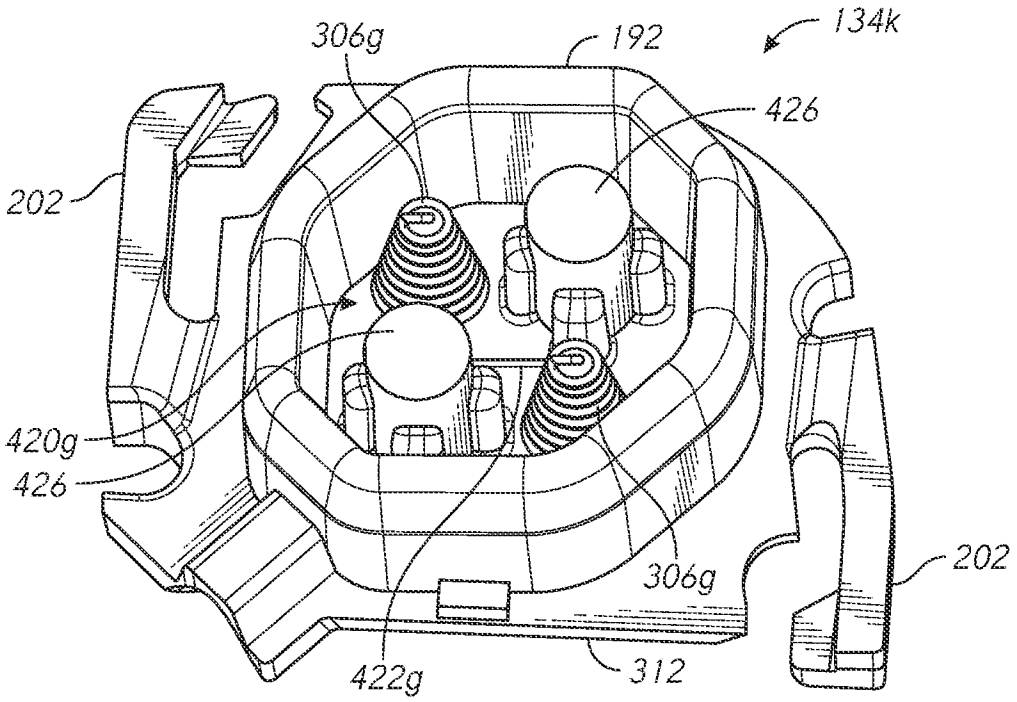

306g
192
134k
426
202
420g
426
306g
202
422g
312

FIG. 67

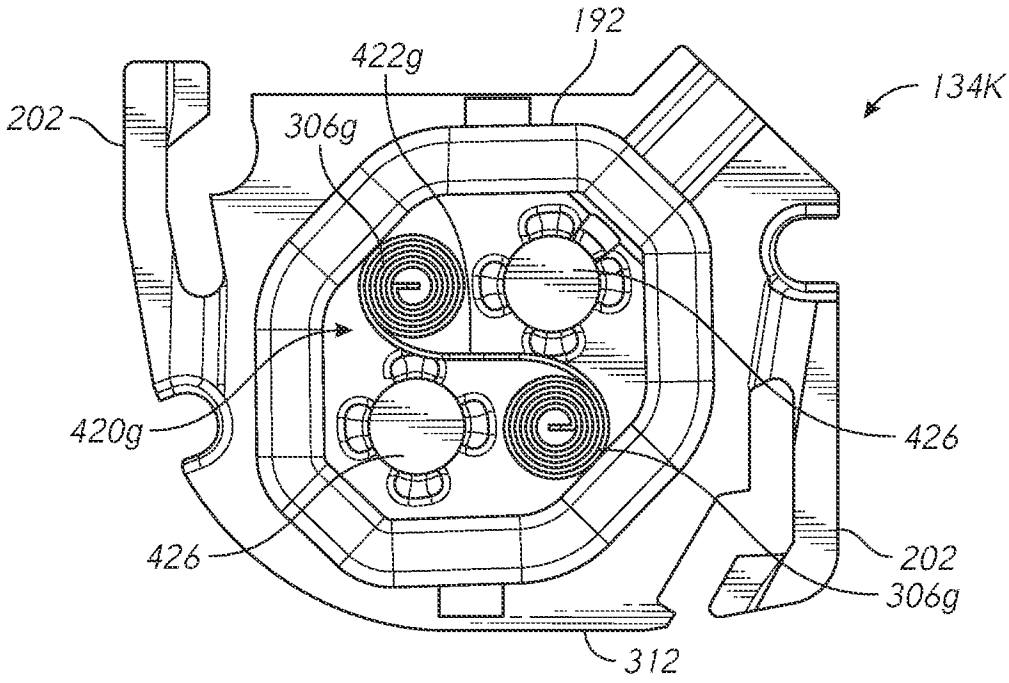

192
422g
134K
202
306g
420g
426
426
202
306g
312

FIG. 68

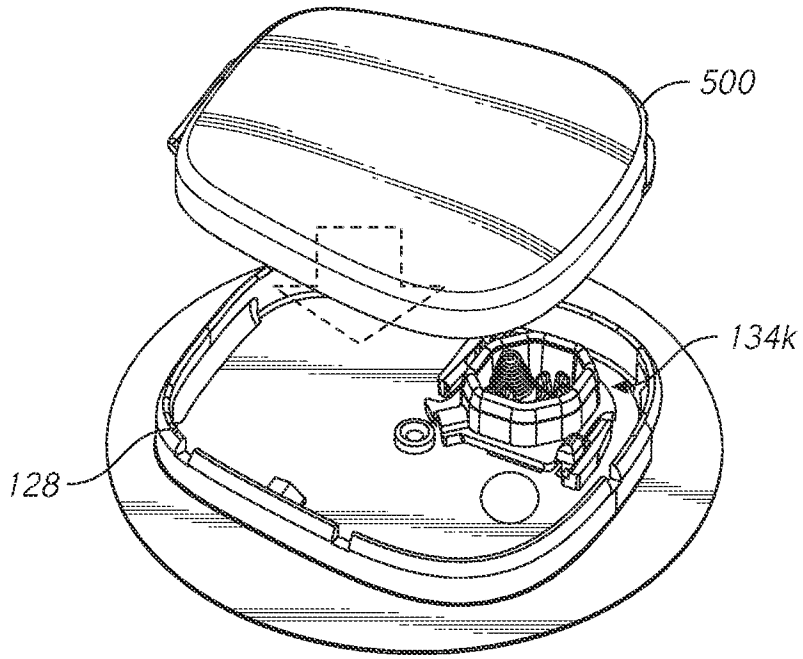


FIG. 69

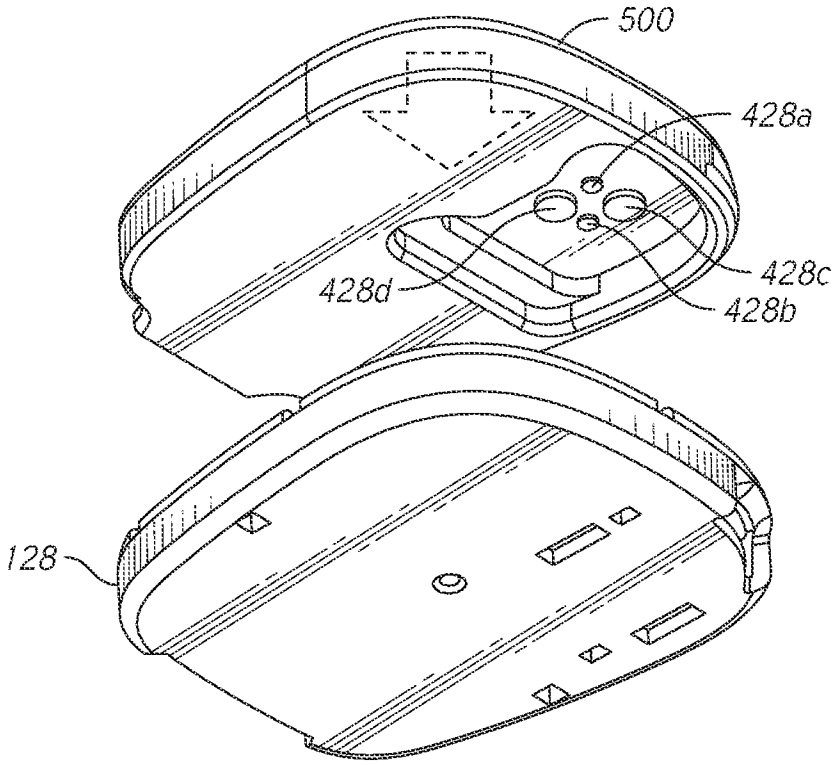


FIG. 70

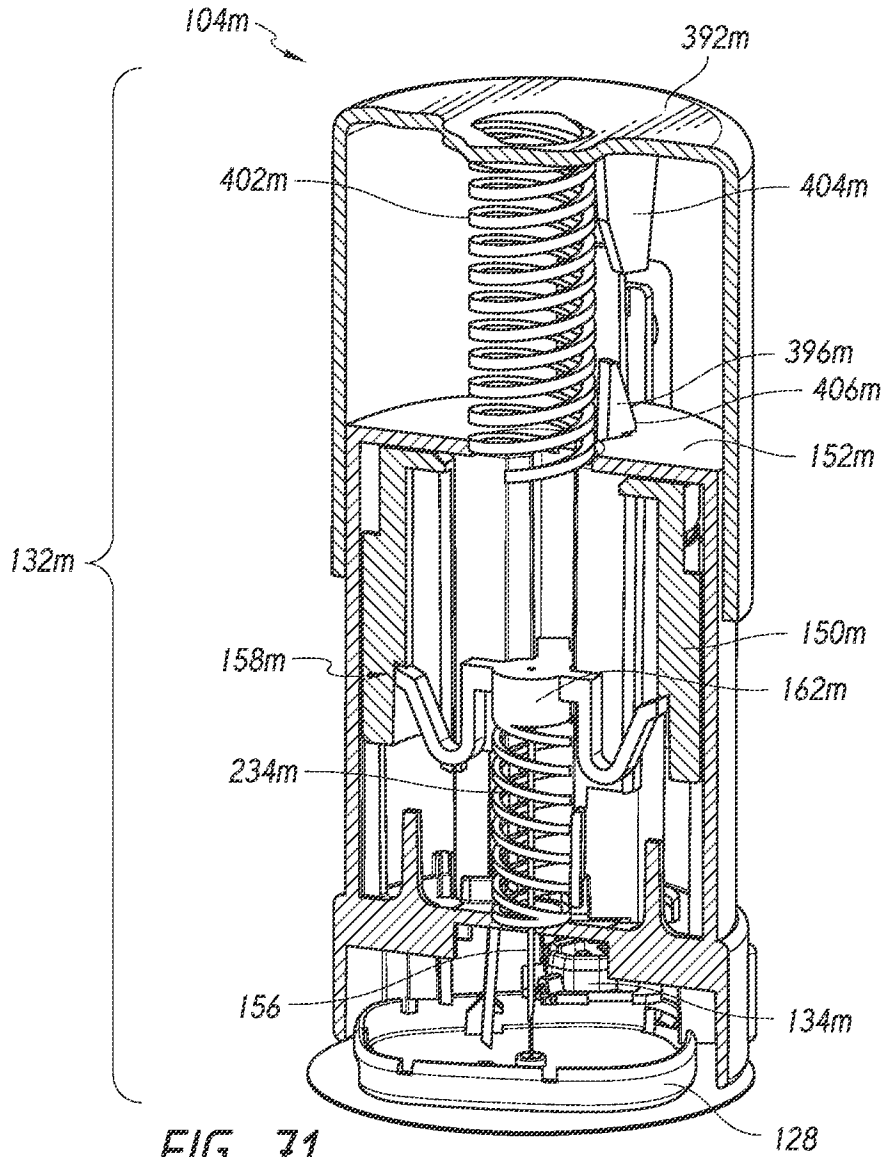

104m
392m
402m
404m
396m
406m
152m
132m
150m
158m
162m
234m
156
134m
128

FIG. 71

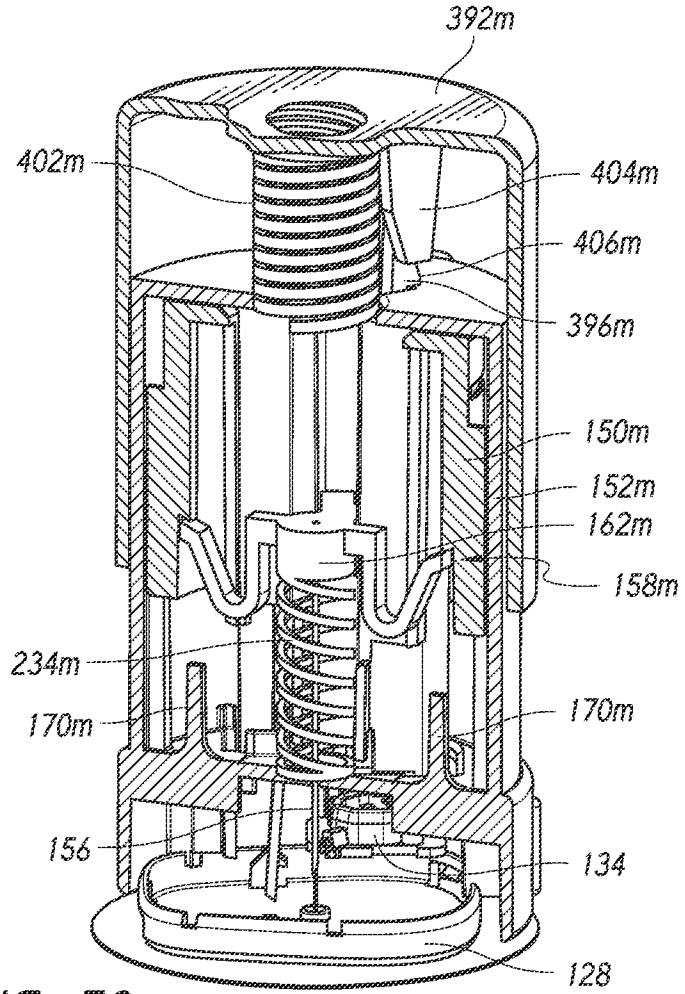

392m
402m
404m
406m
396m
150m
152m
162m
158m
234m
170m
170m
156
134
128

FIG. 72

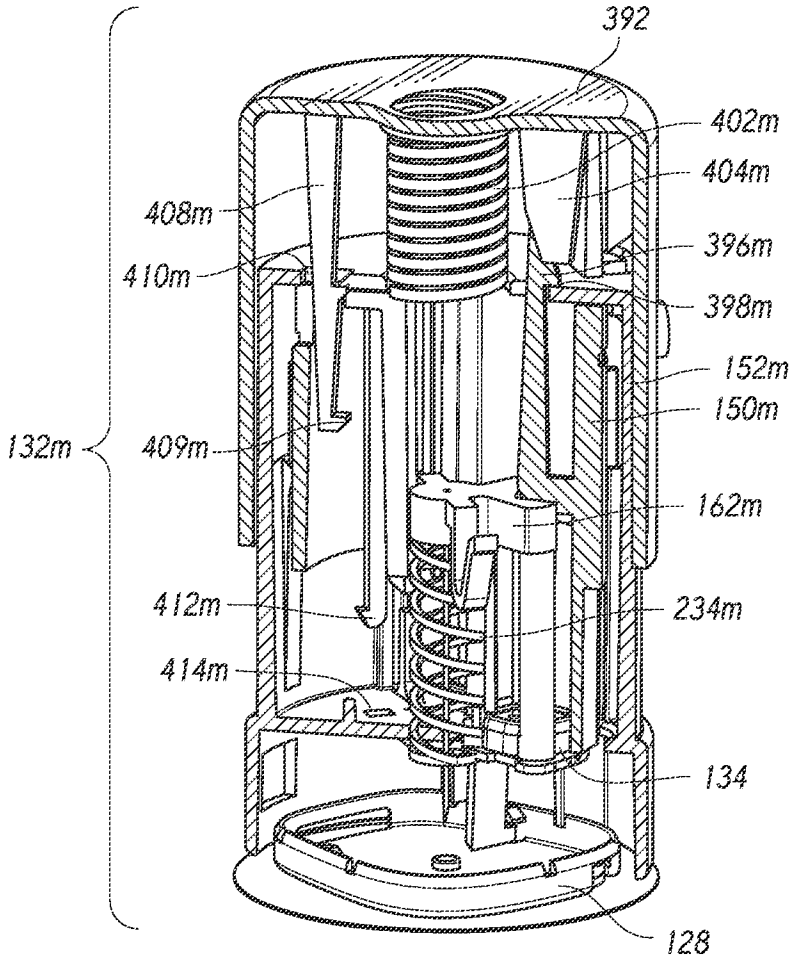

392
402m
404m
408m
410m
396m
398m
152m
150m
132m
409m
162m
412m
234m
414m
134
128

FIG. 73

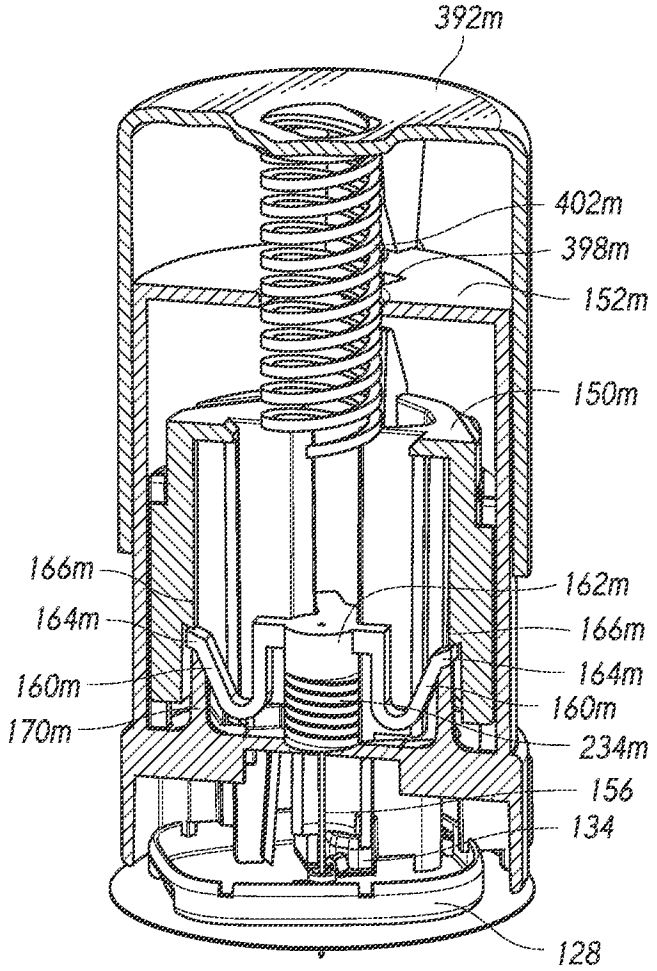

392m
402m
398m
152m
150m
166m
162m
164m
166m
160m
164m
170m
160m
234m
156
134
128

FIG. 74

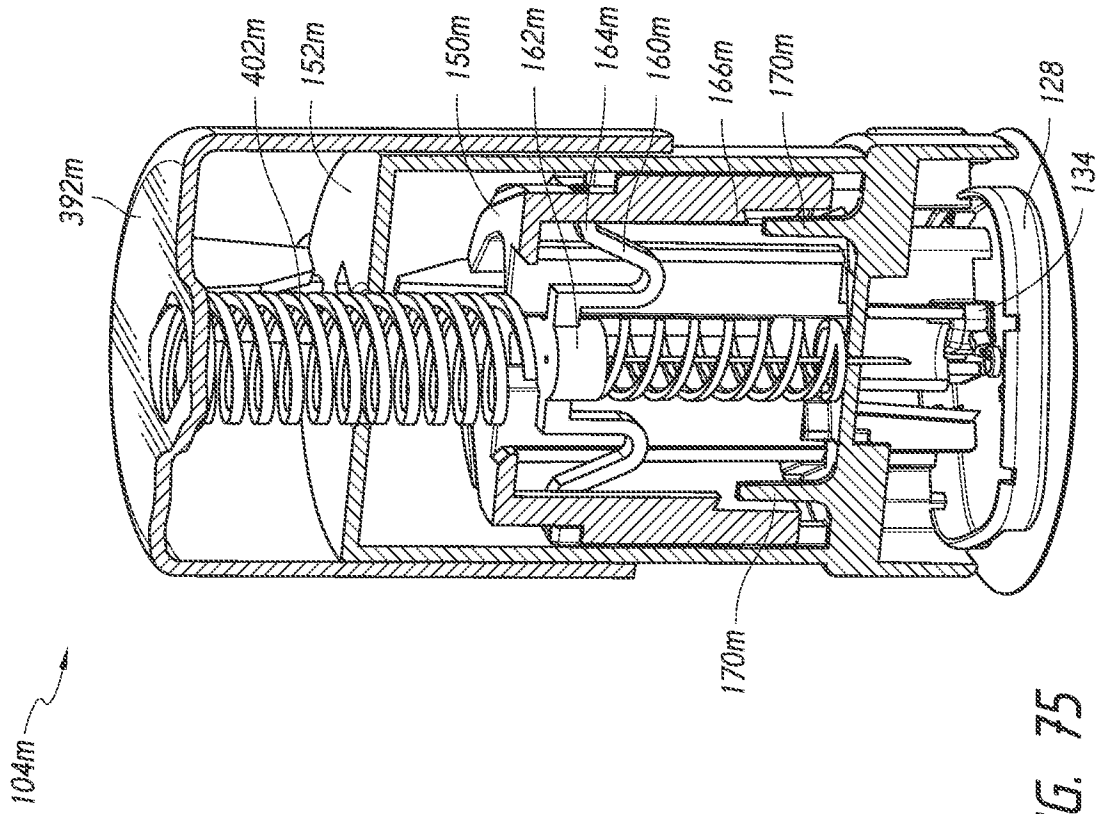

402m
152m
150m
162m
164m
160m
166m
170m
128
134
392m
170m
104m

FIG. 75

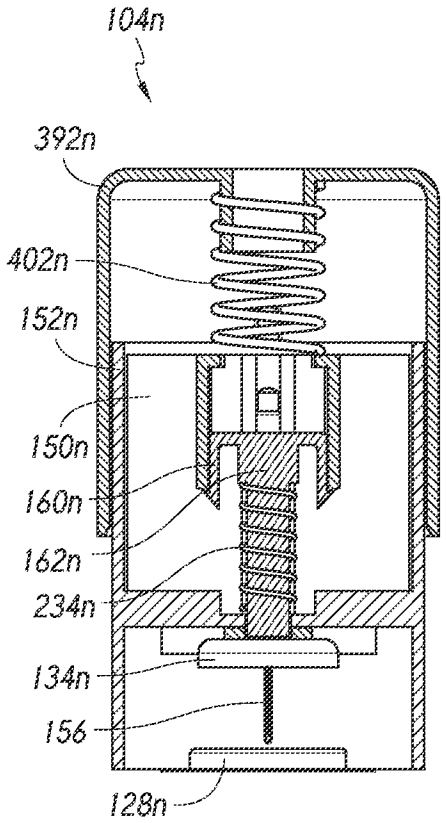


FIG. 76

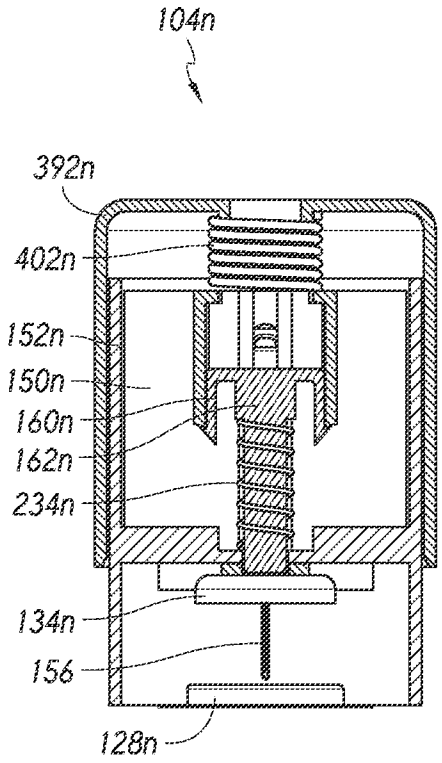


FIG. 77

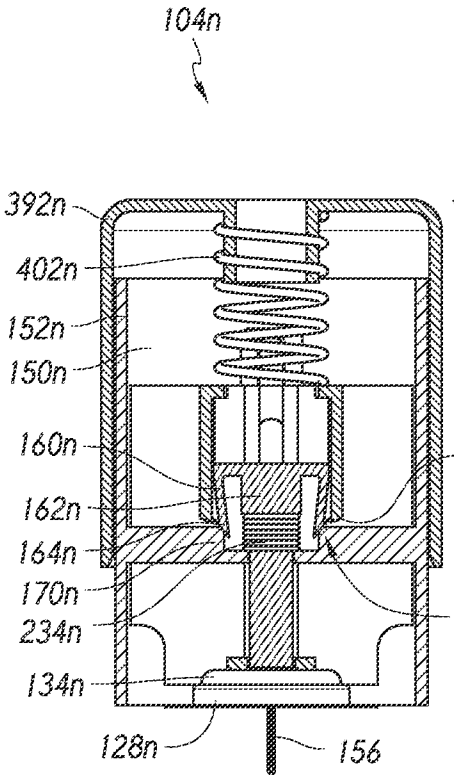


FIG. 78

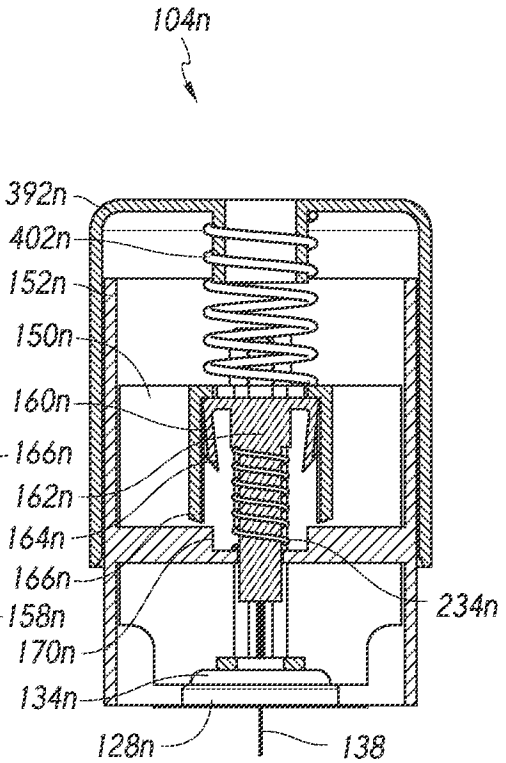


FIG. 79

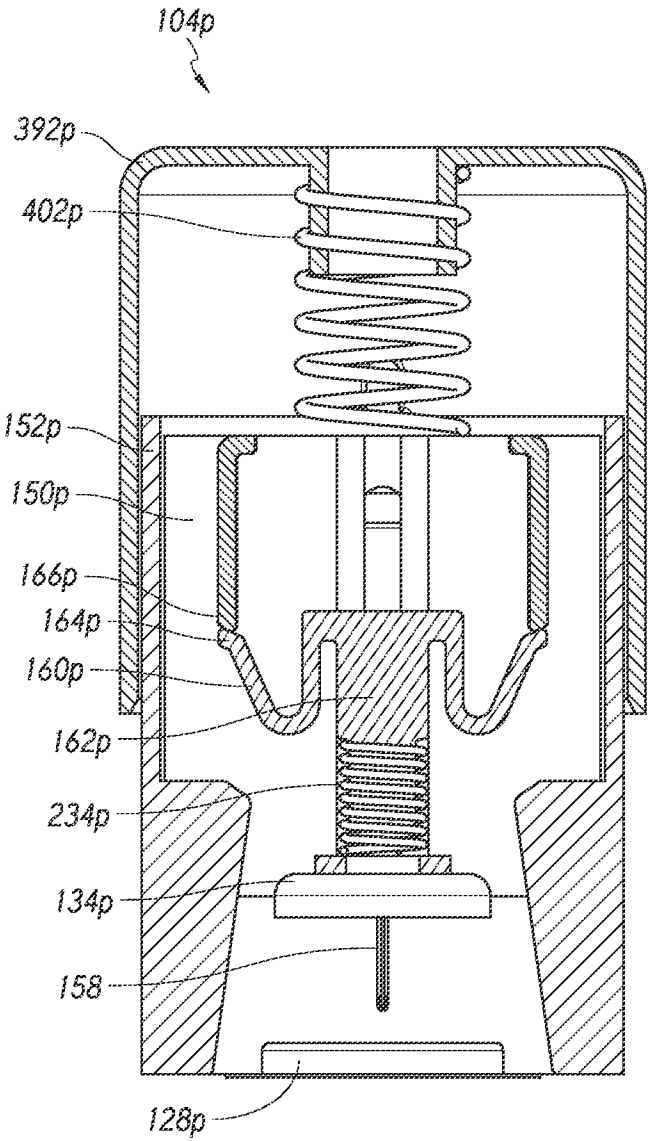

104p
392p
402p
152p
150p
166p
164p
160p
162p
234p
134p
158
128p

FIG. 80

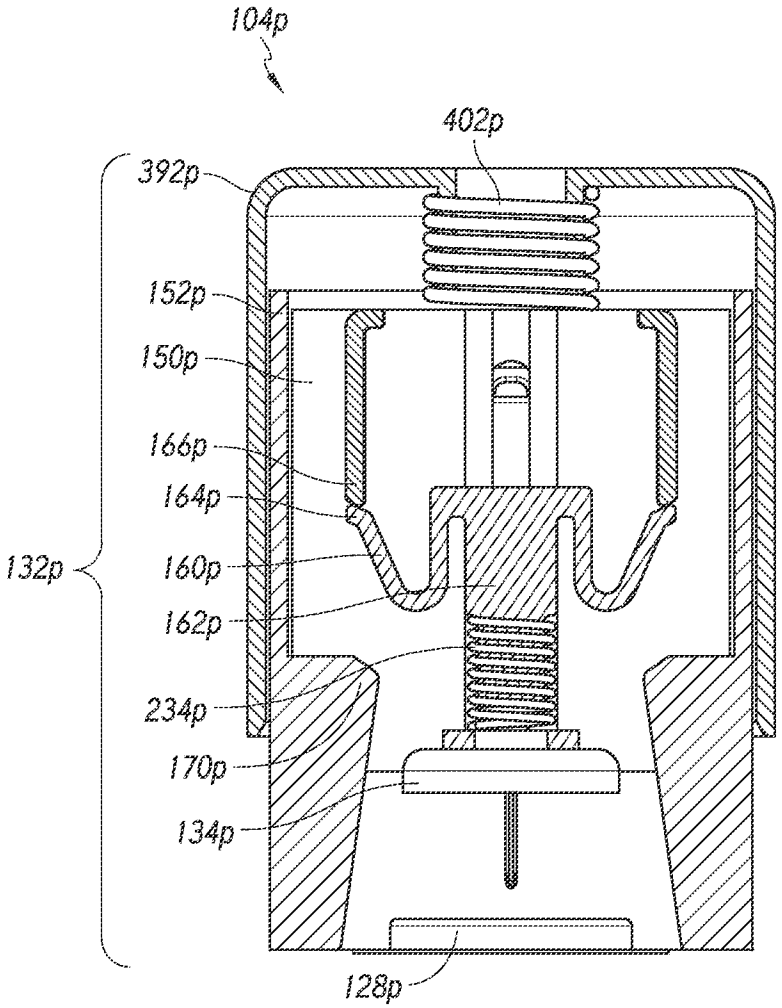

104p
402p
392p
152p
150p
166p
164p
132p
160p
162p
234p
170p
134p
128p

FIG. 81

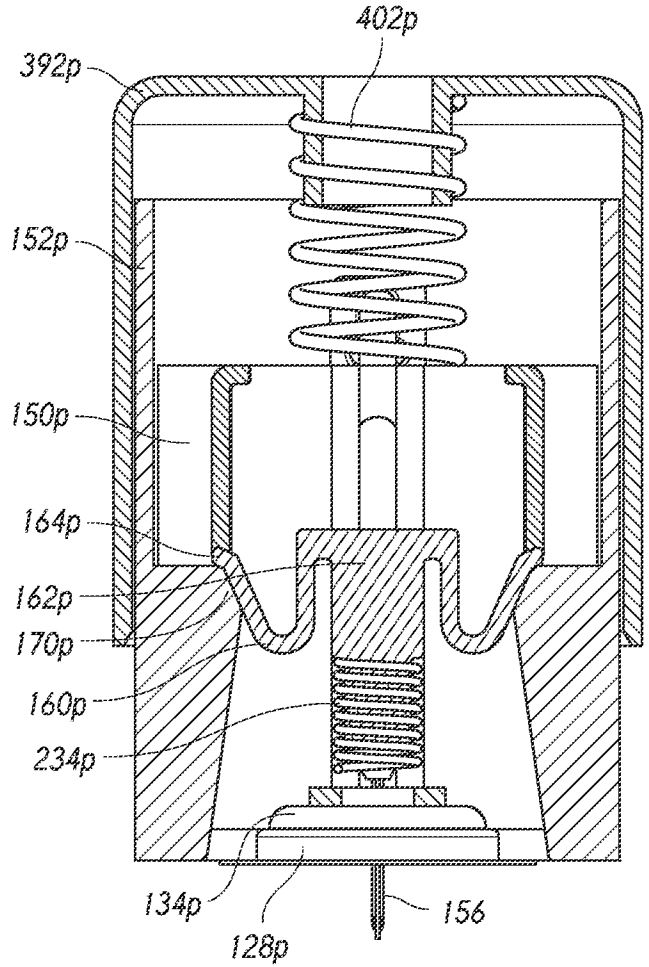

402p
392p
152p
150p
164p
162p
170p
160p
234p
134p
128p
156

FIG. 82

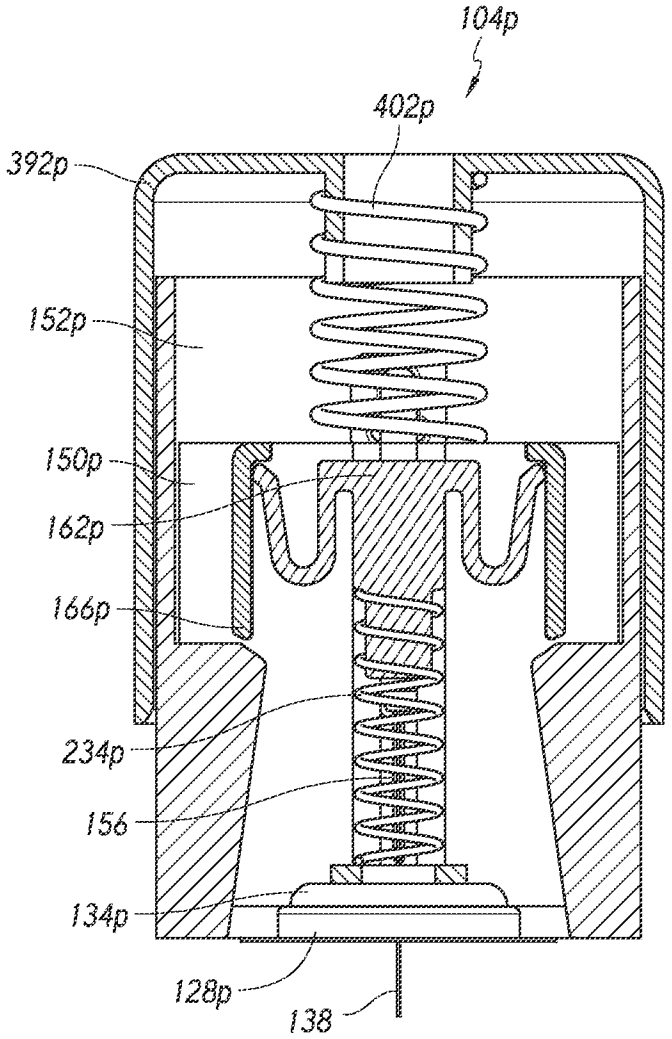

104p
402p
392p
152p
150p
162p
166p
234p
156
134p
128p
138

FIG. 83

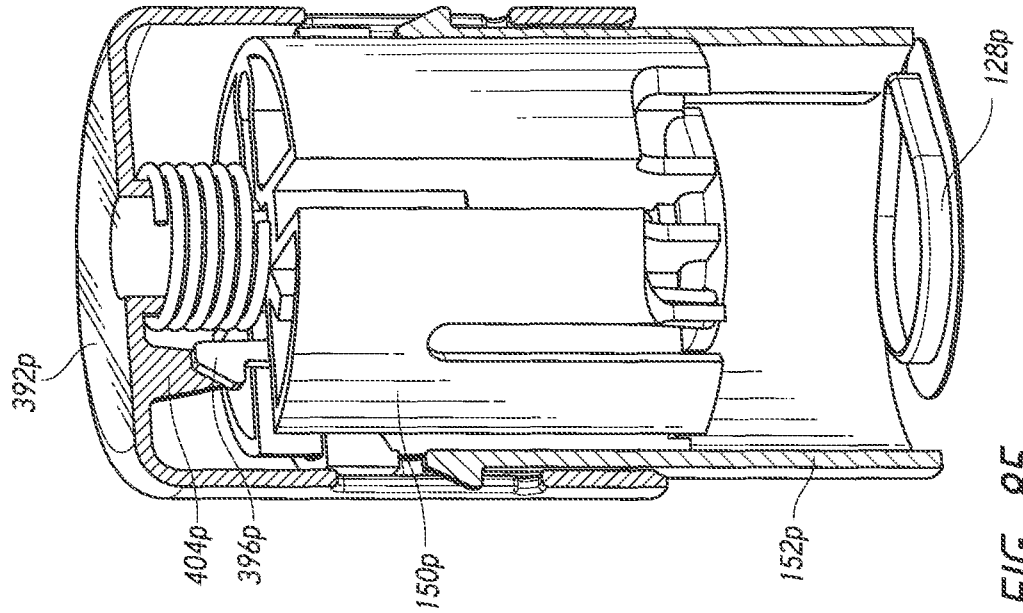

392p
404p
396p
150p
152p
128p

FIG. 85

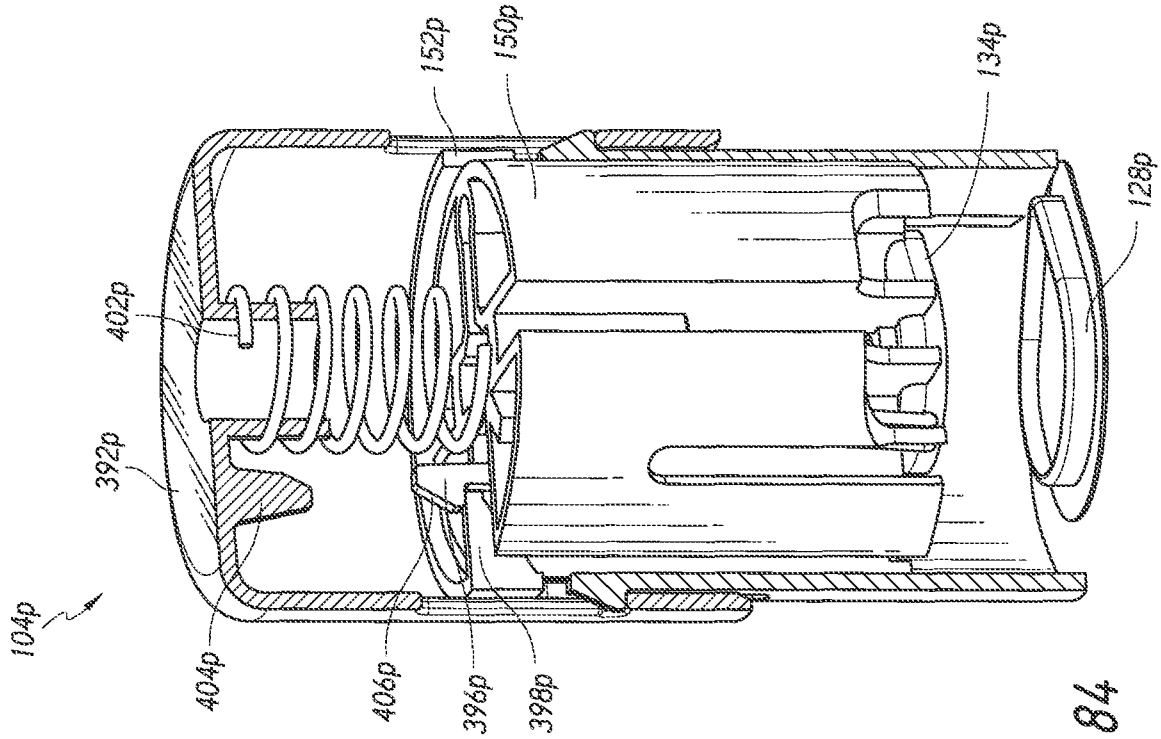

104p
402p
392p
404p
406p
396p
398p
152p
150p
134p
128p

FIG. 84

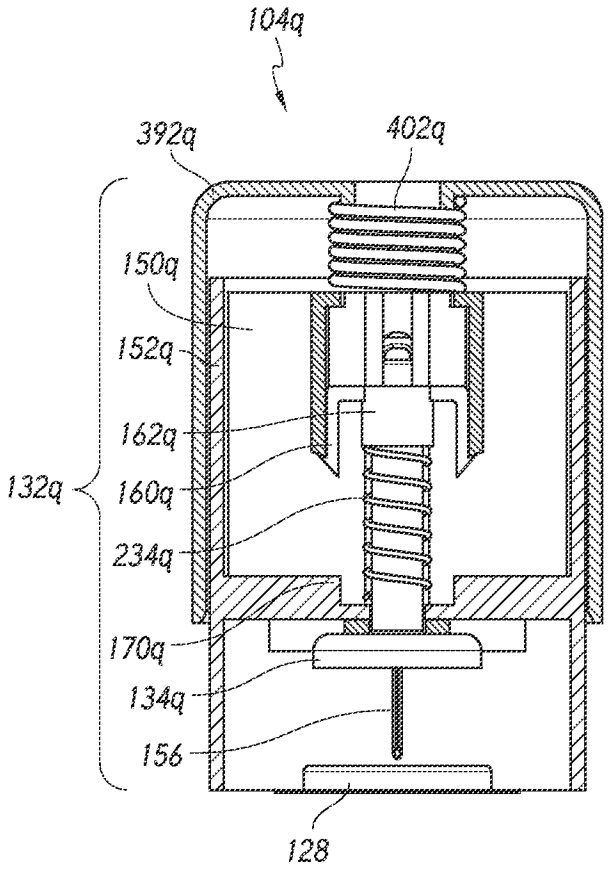


FIG. 86

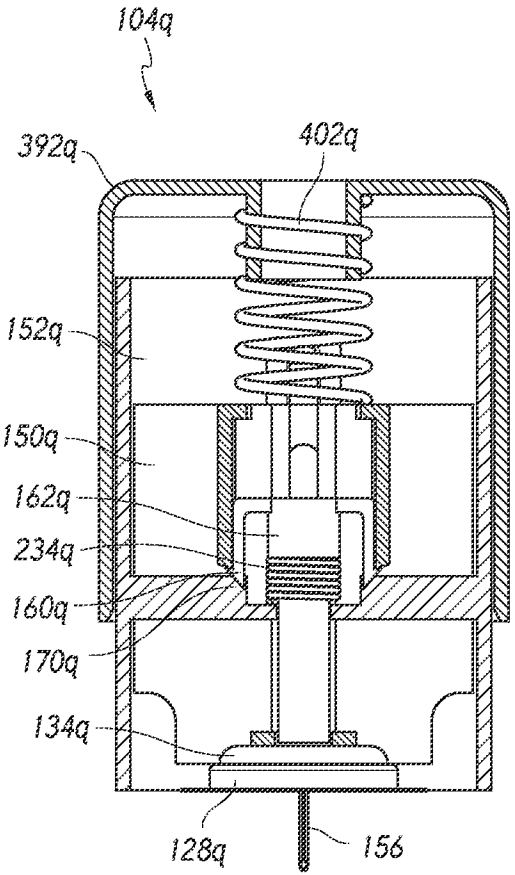


FIG. 87

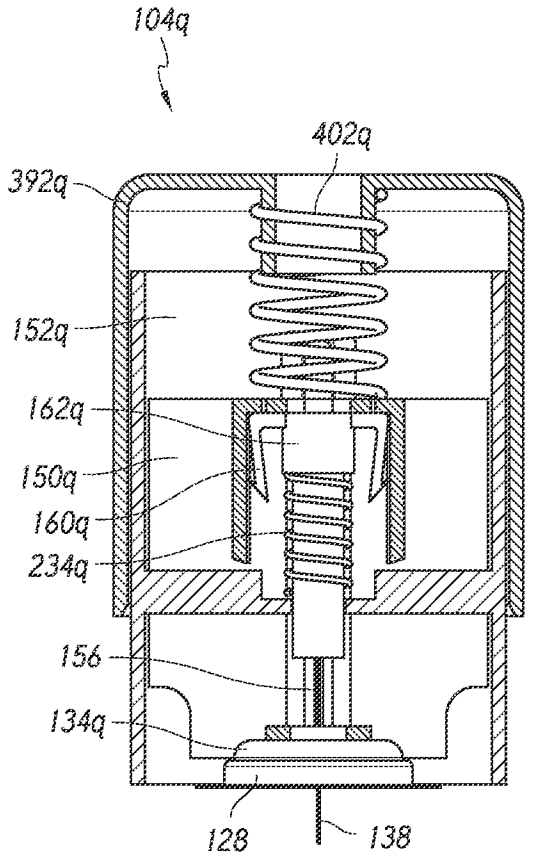


FIG. 88

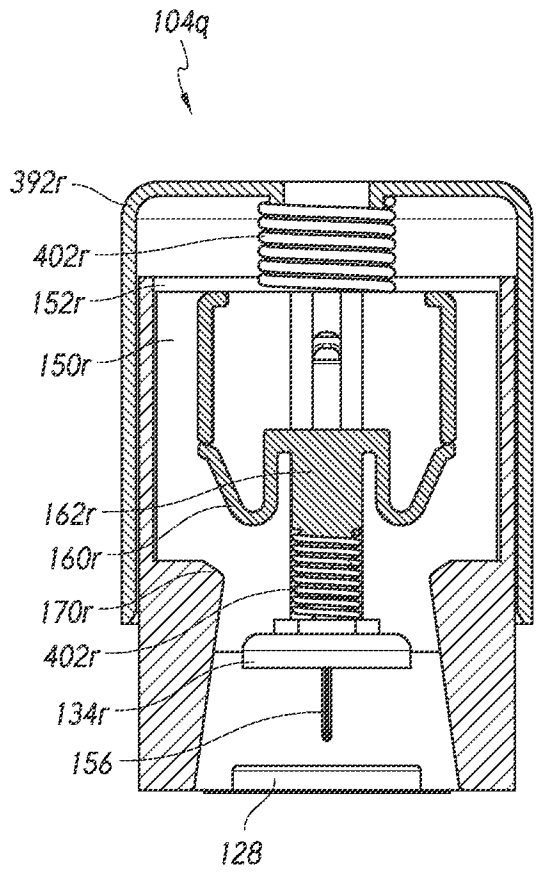


FIG. 89

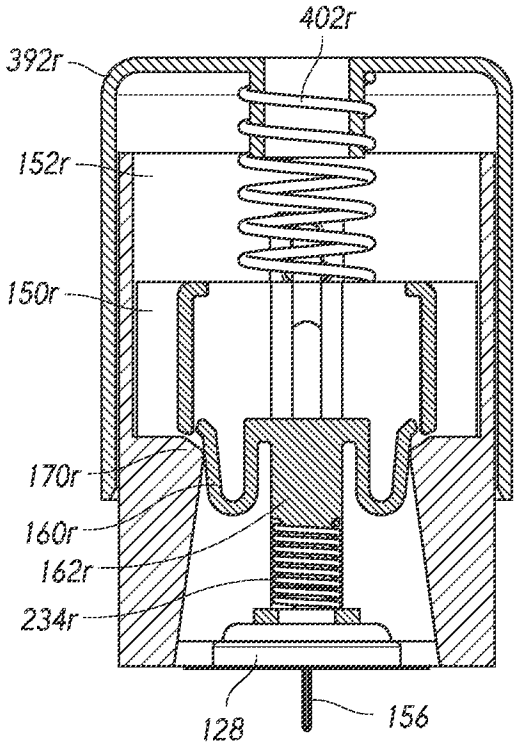


FIG. 90

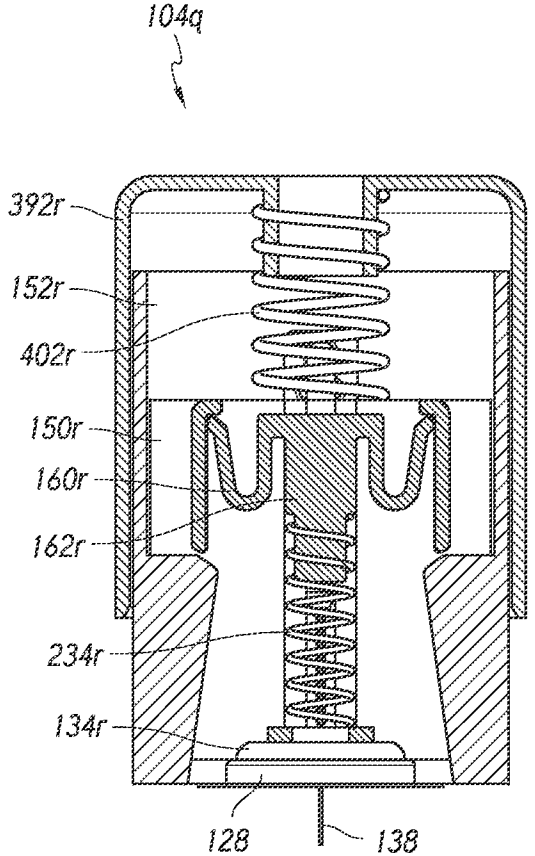


FIG. 91

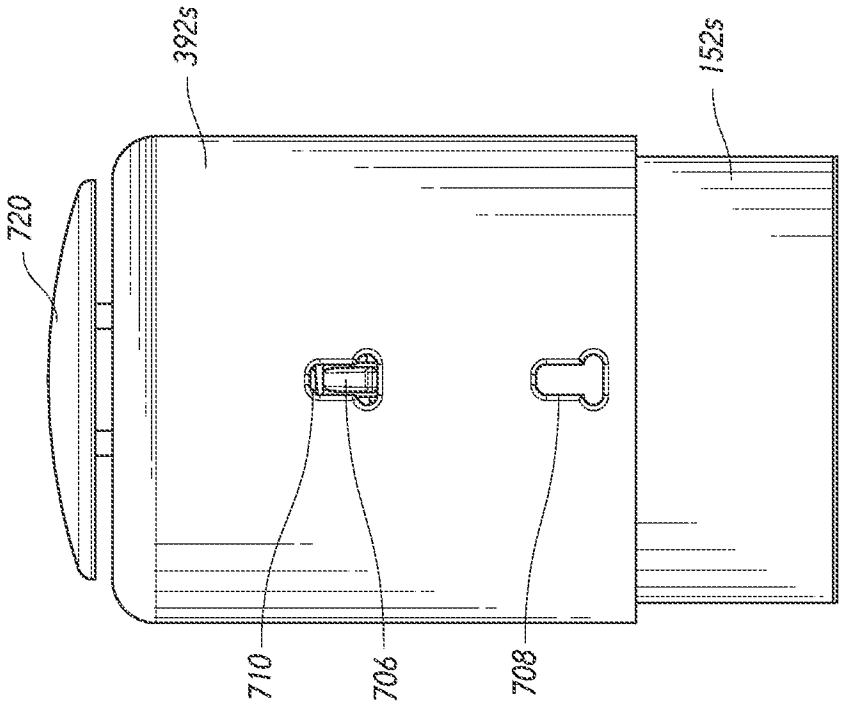

392s
152s
720
710
706
708

FIG. 93

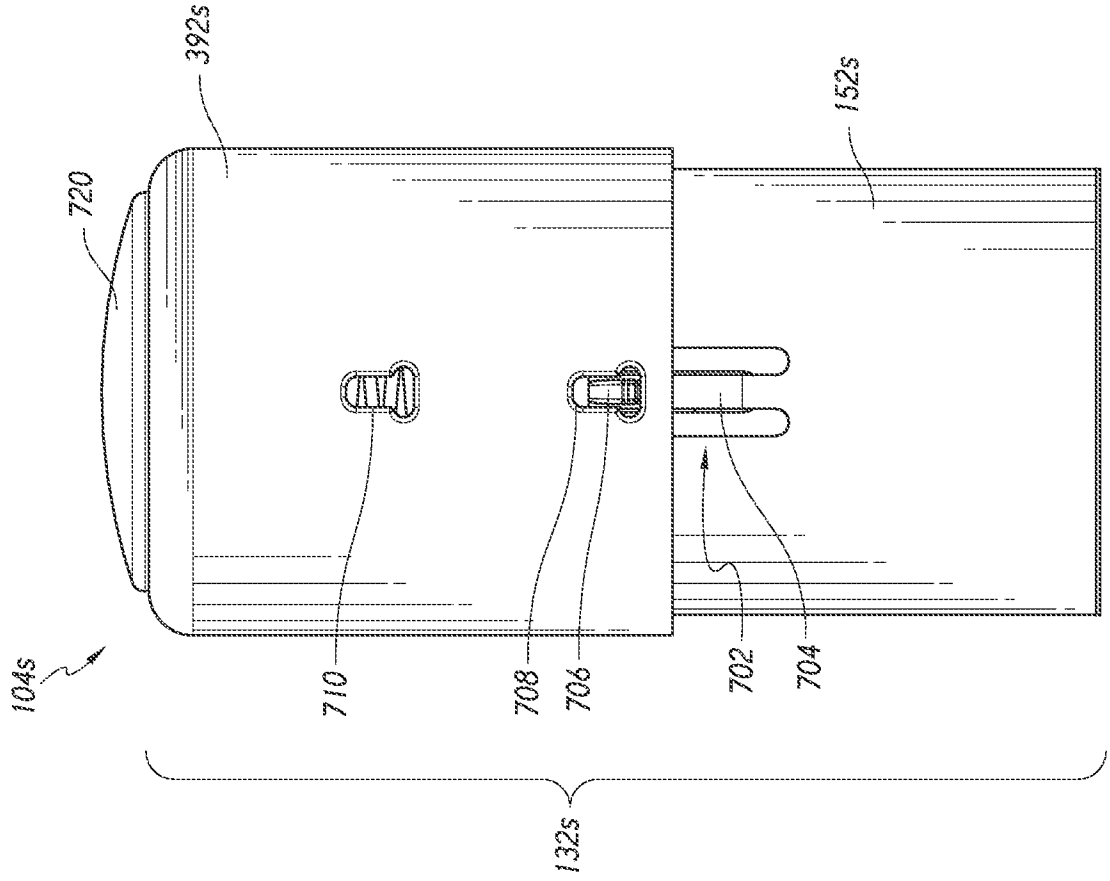

392s
152s
720
104s
710
708
706
702
704
132s

FIG. 92

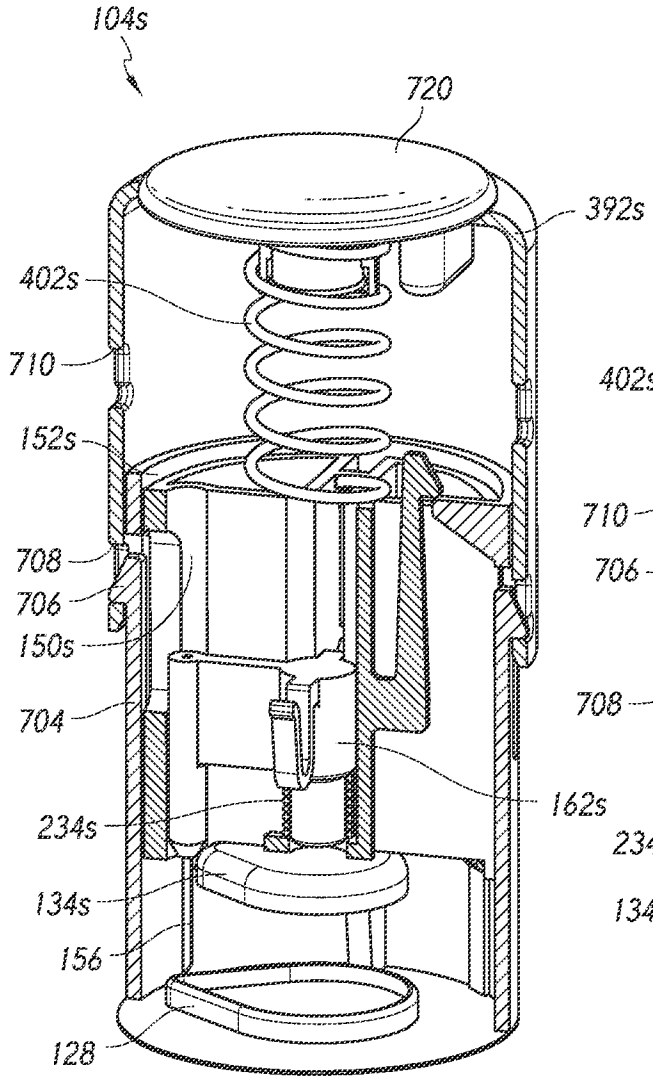


FIG. 94

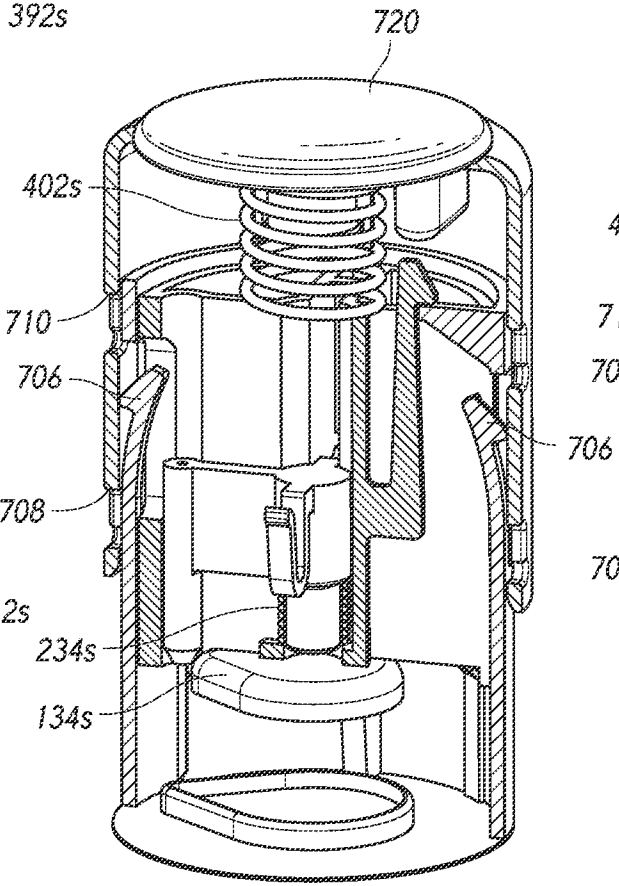


FIG. 95

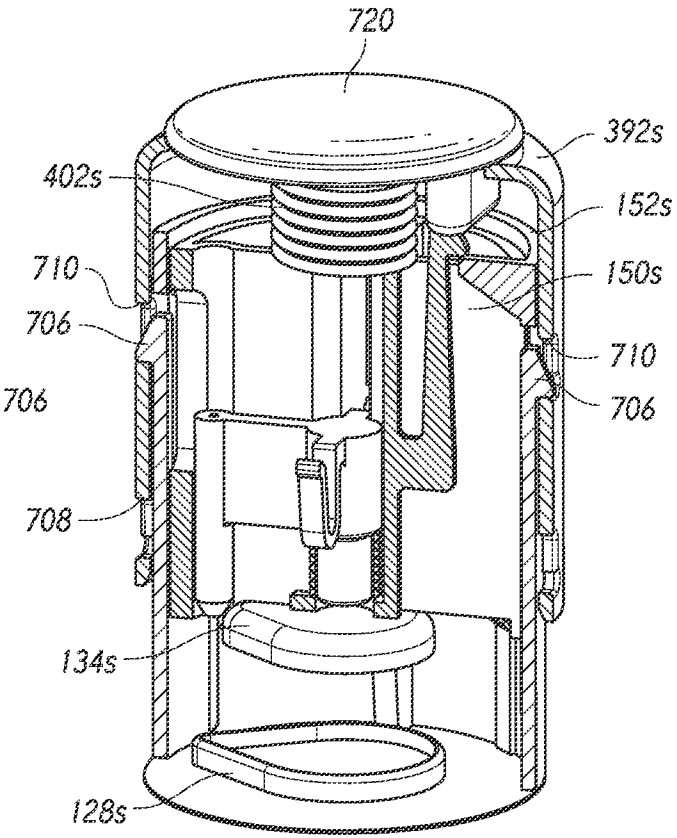


FIG. 96

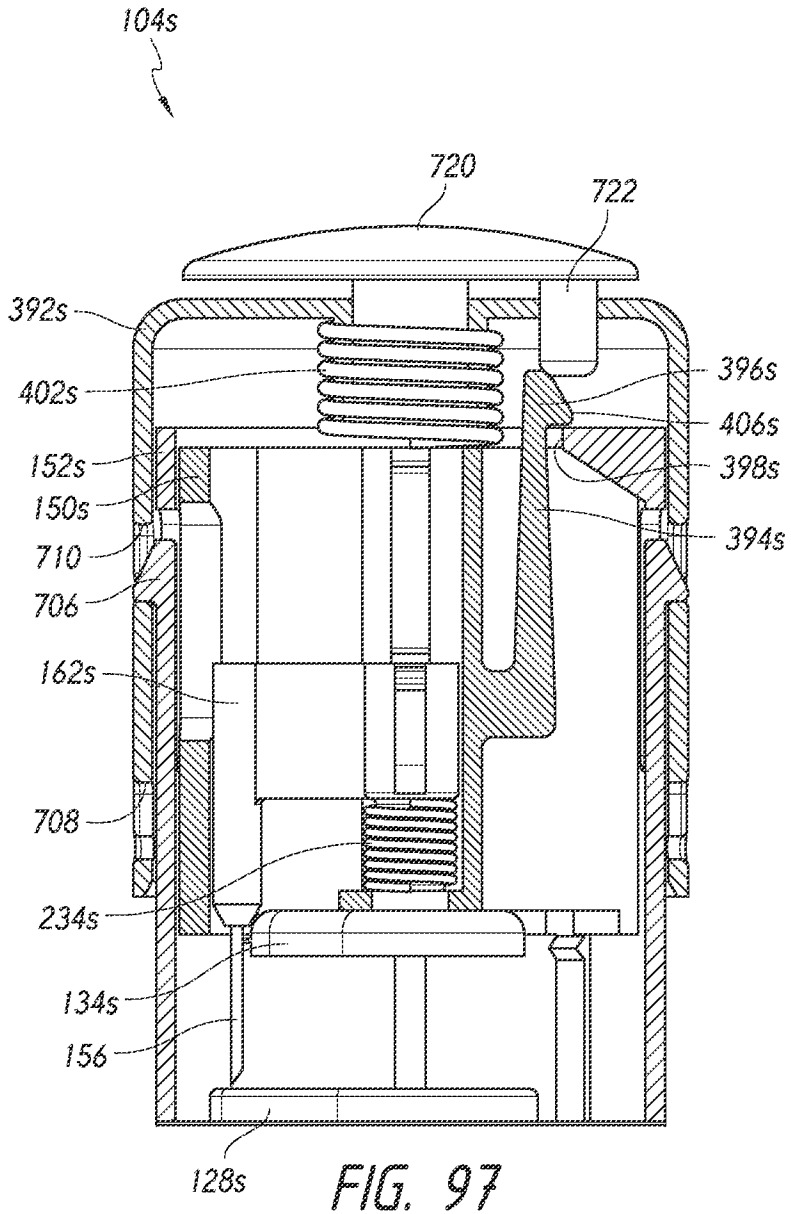

104s
720
722
392s
402s
396s
406s
152s
398s
150s
394s
710
706
162s
708
234s
134s
156
128s

FIG. 97

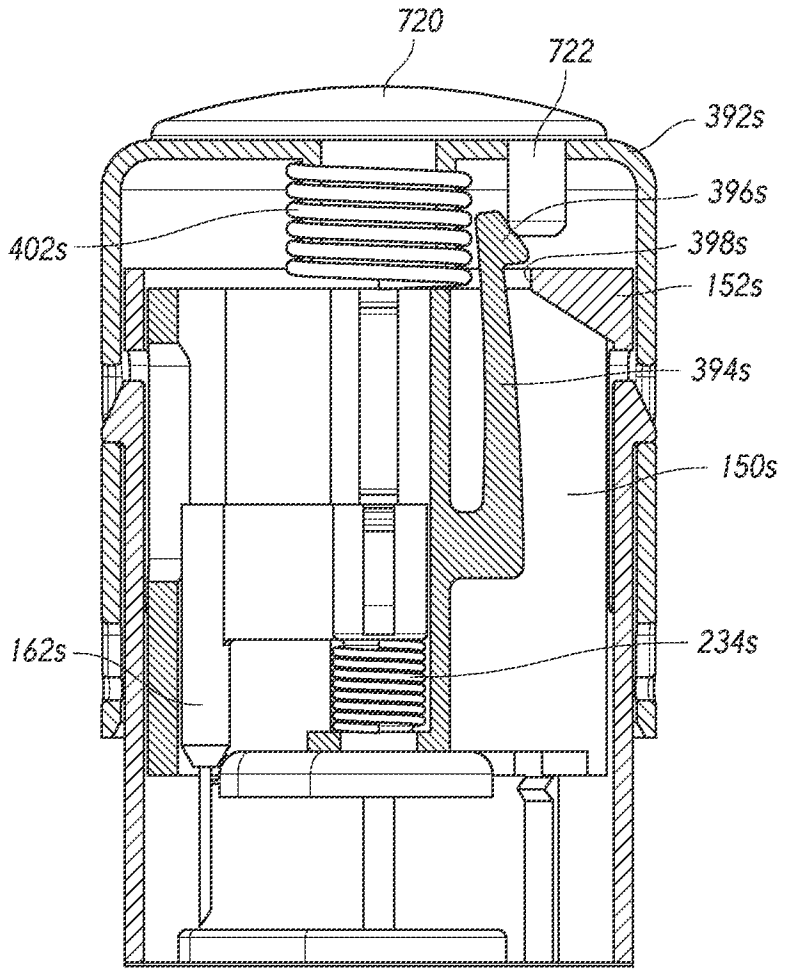

720
722
392s
396s
402s
398s
152s
394s
150s
162s
234s

FIG. 98

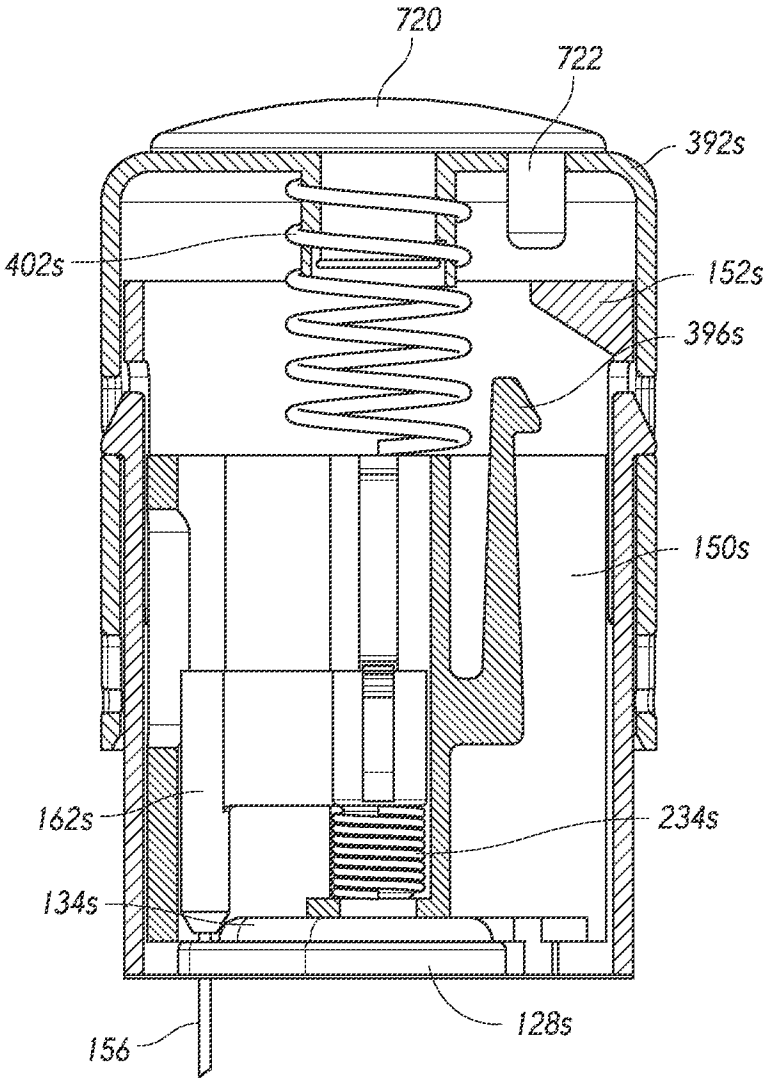


FIG. 99

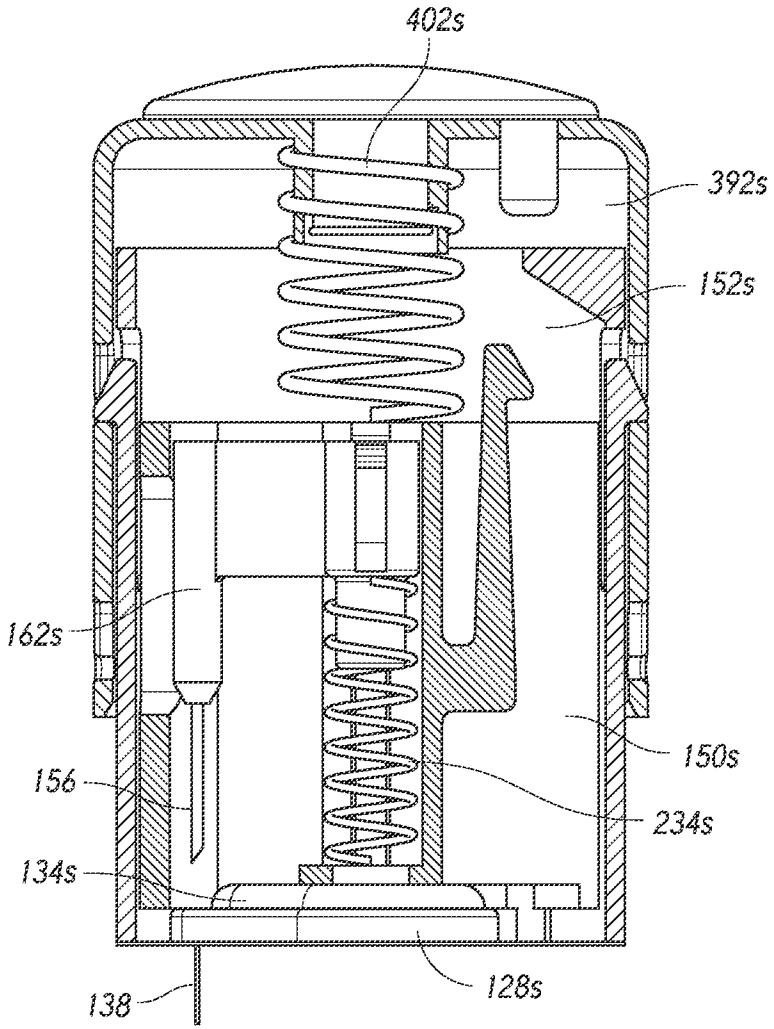


FIG. 100

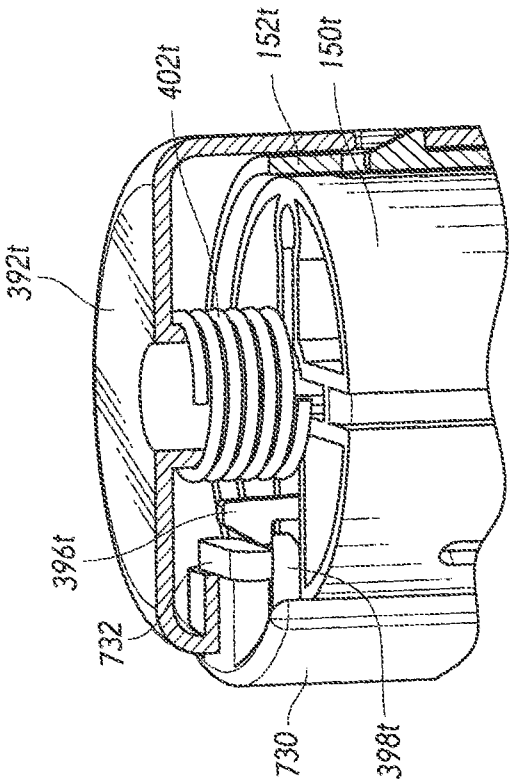


FIG. 102

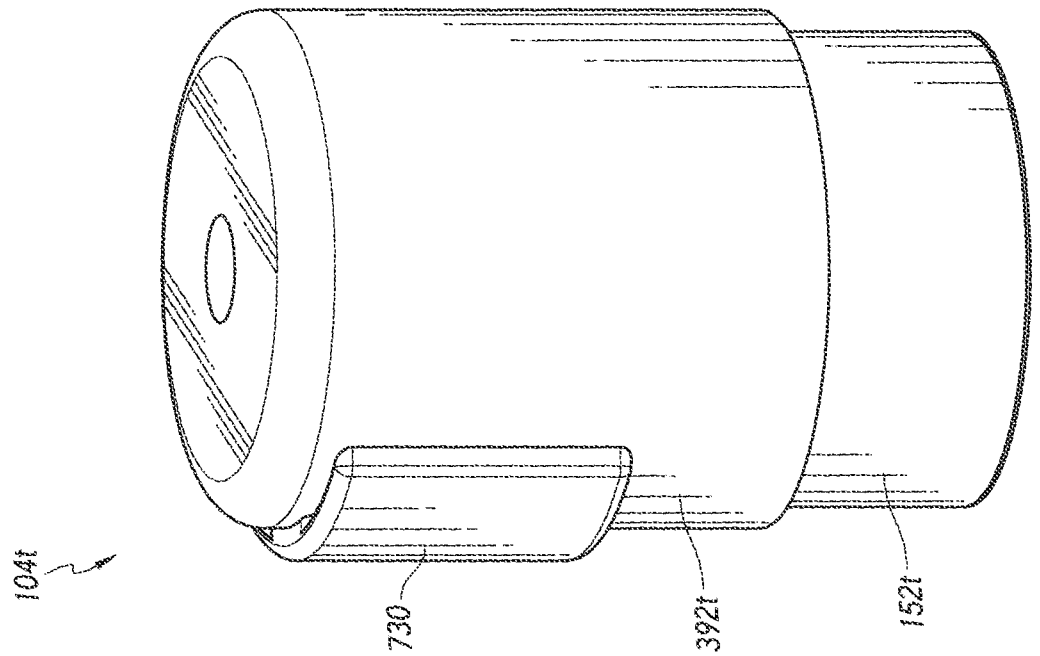


FIG. 101

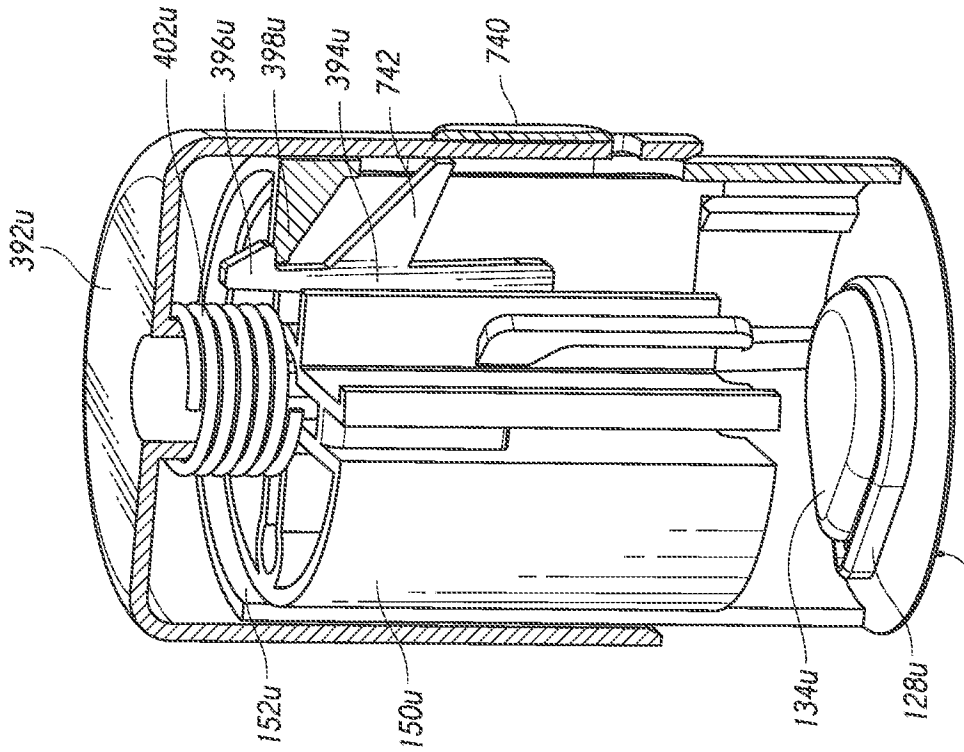


FIG. 104

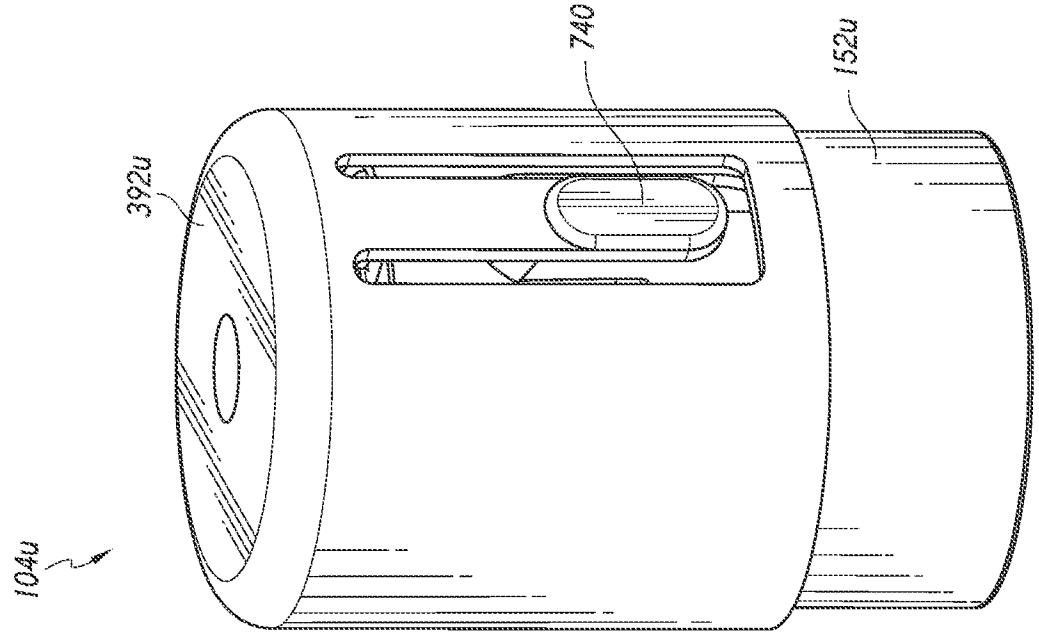


FIG. 103

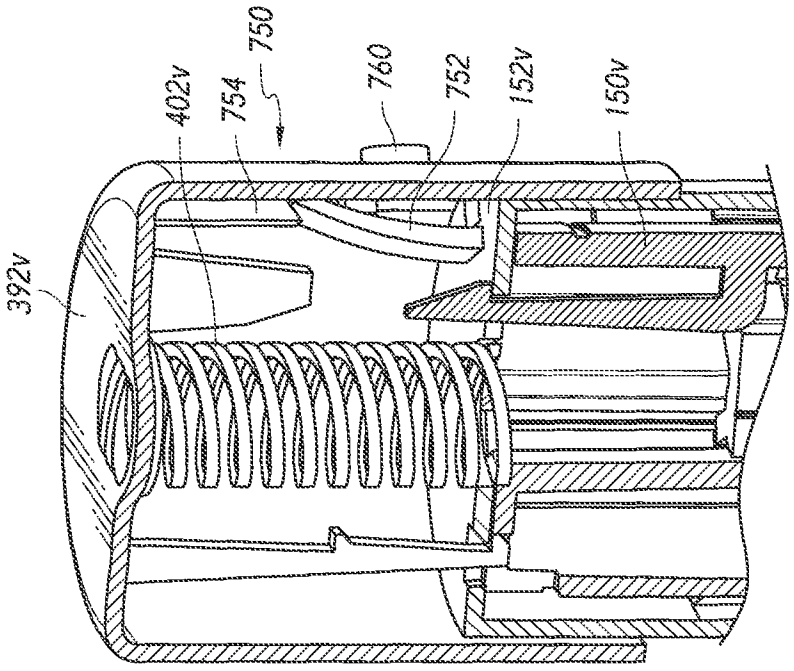


FIG. 106

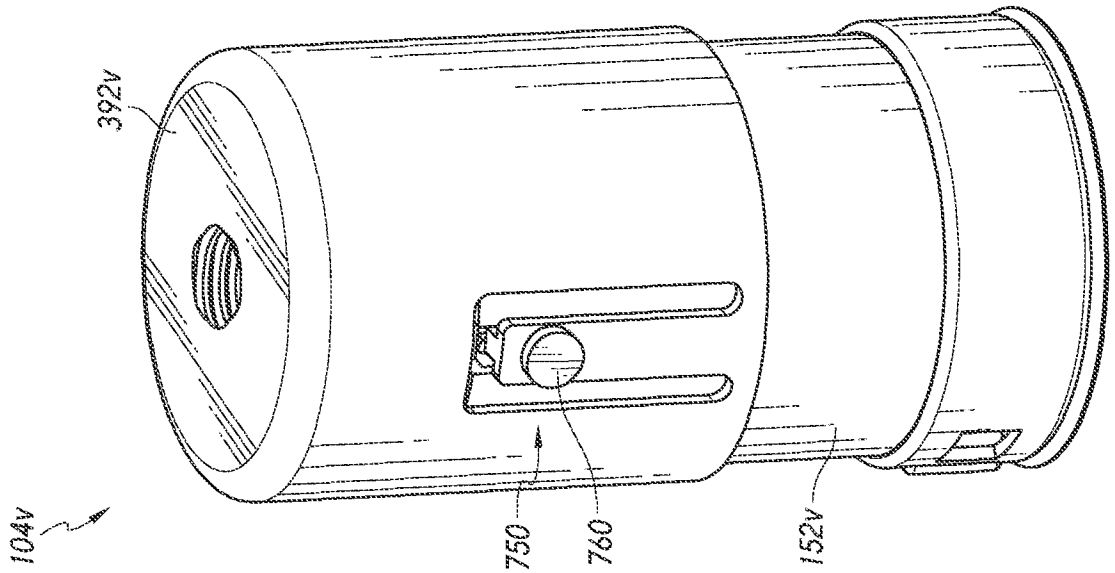


FIG. 105

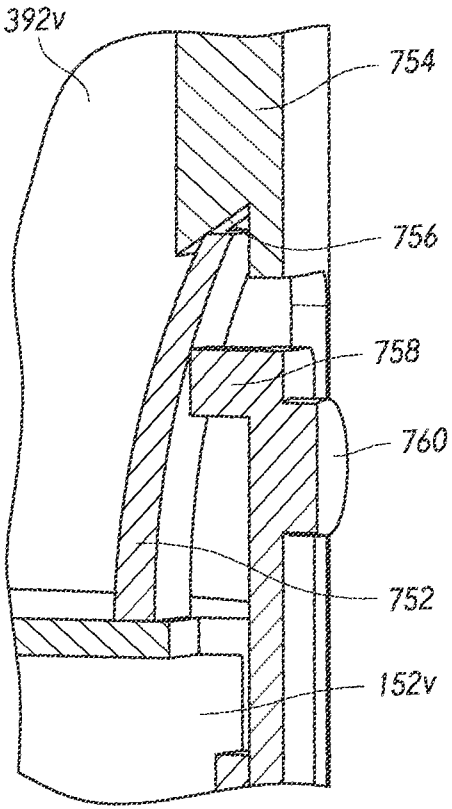


FIG. 107

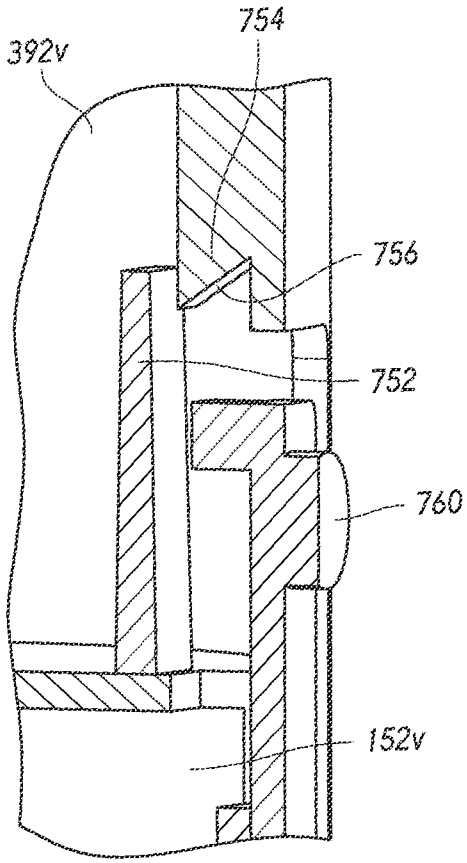


FIG. 108

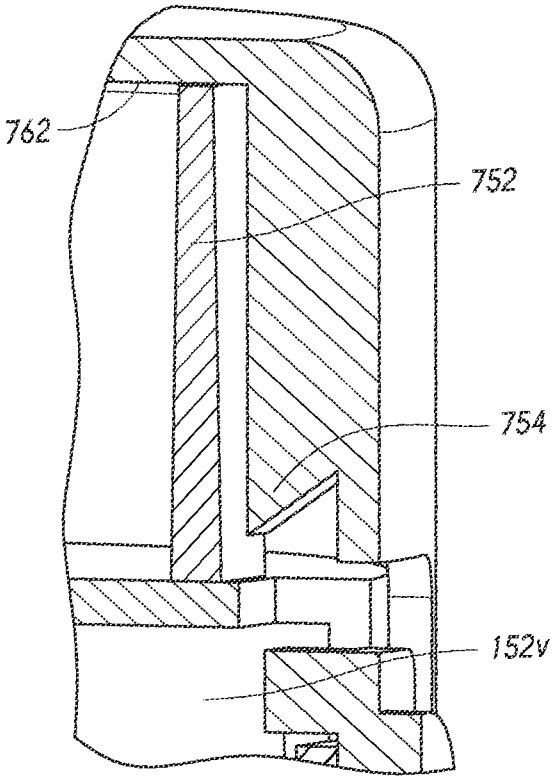


FIG. 109

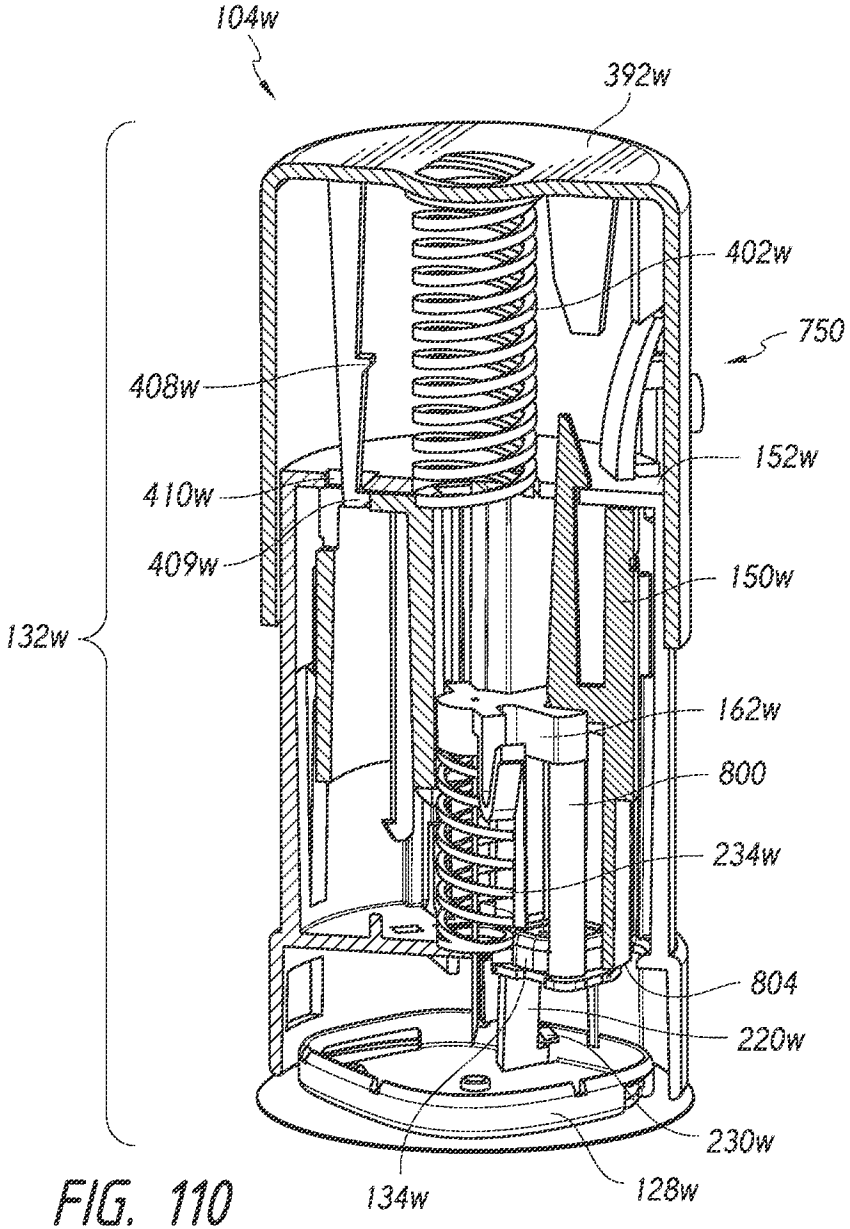


FIG. 110

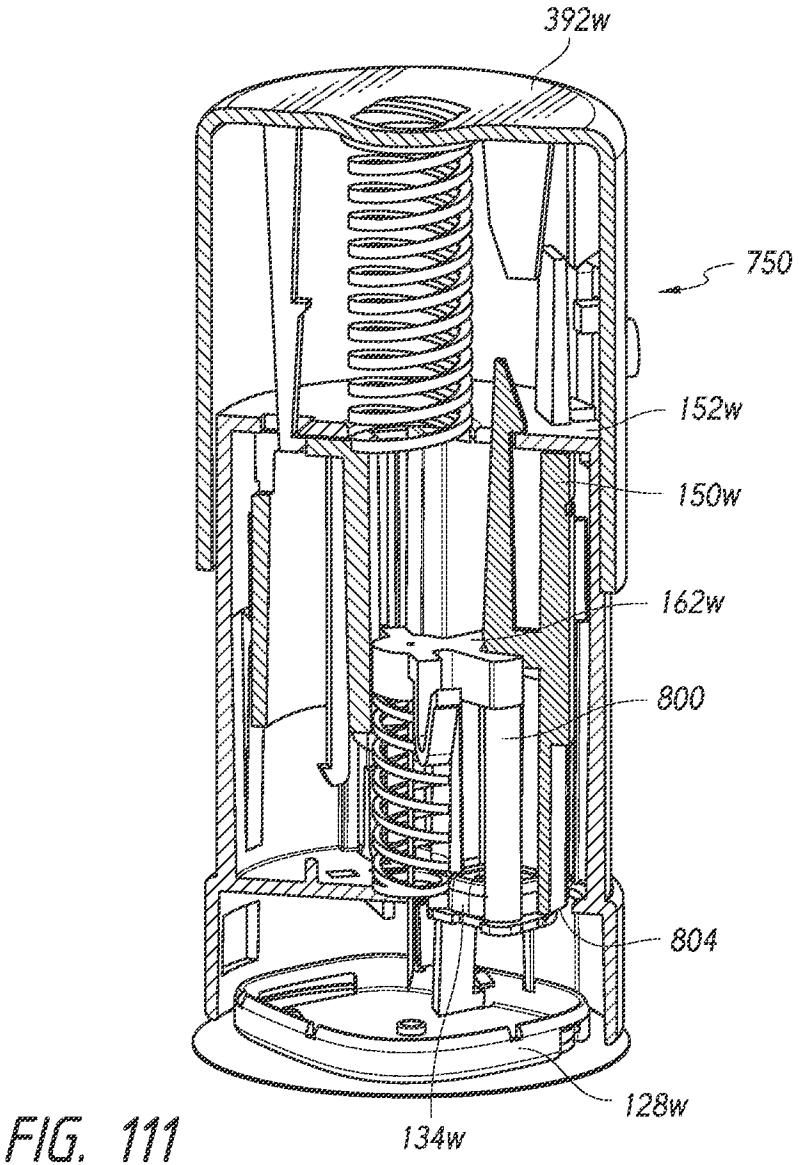


FIG. 111

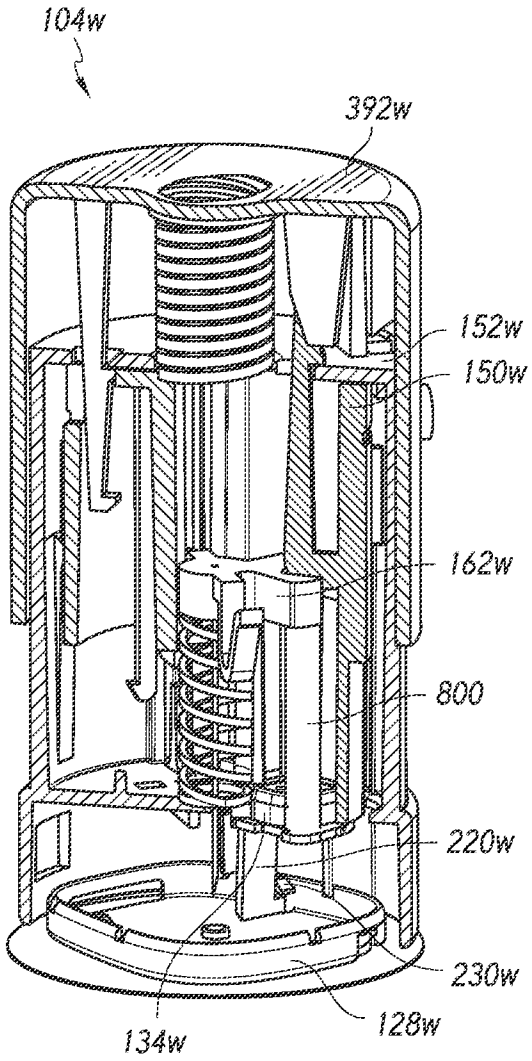


FIG. 112

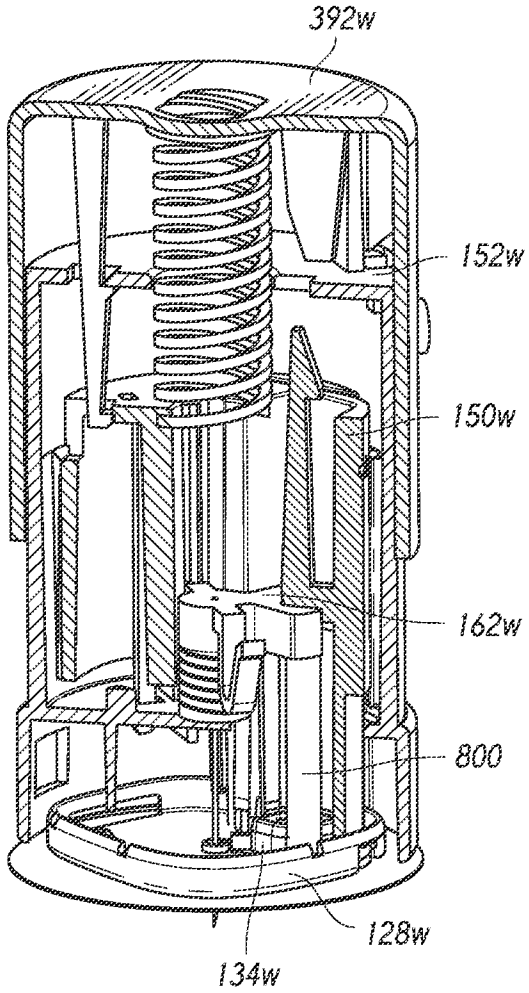


FIG. 113

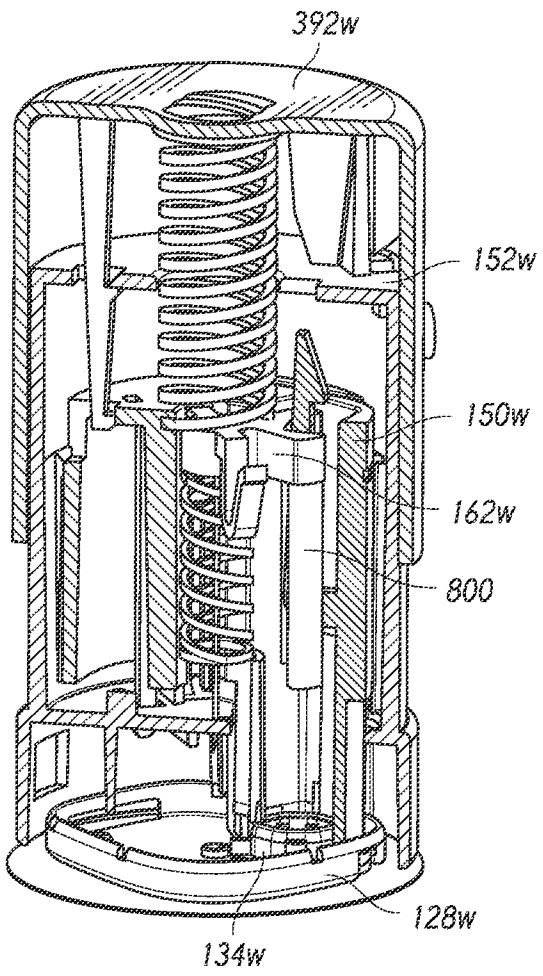


FIG. 114

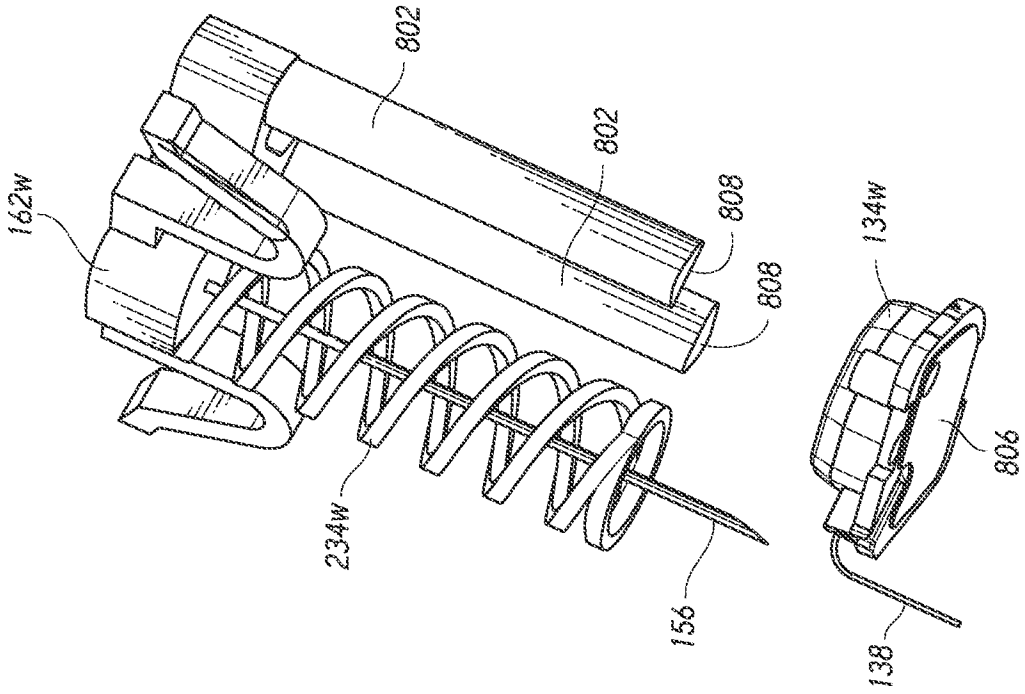


FIG. 116

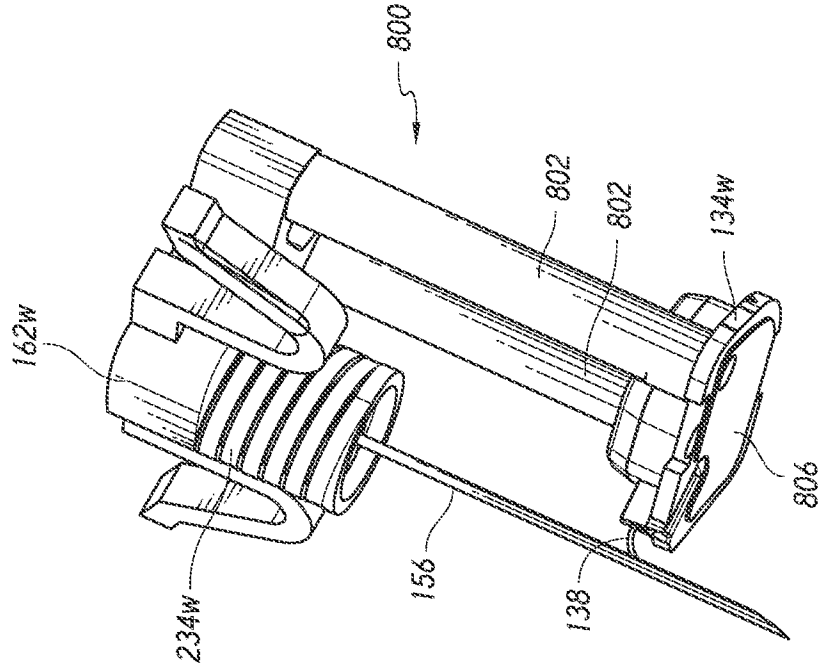


FIG. 115

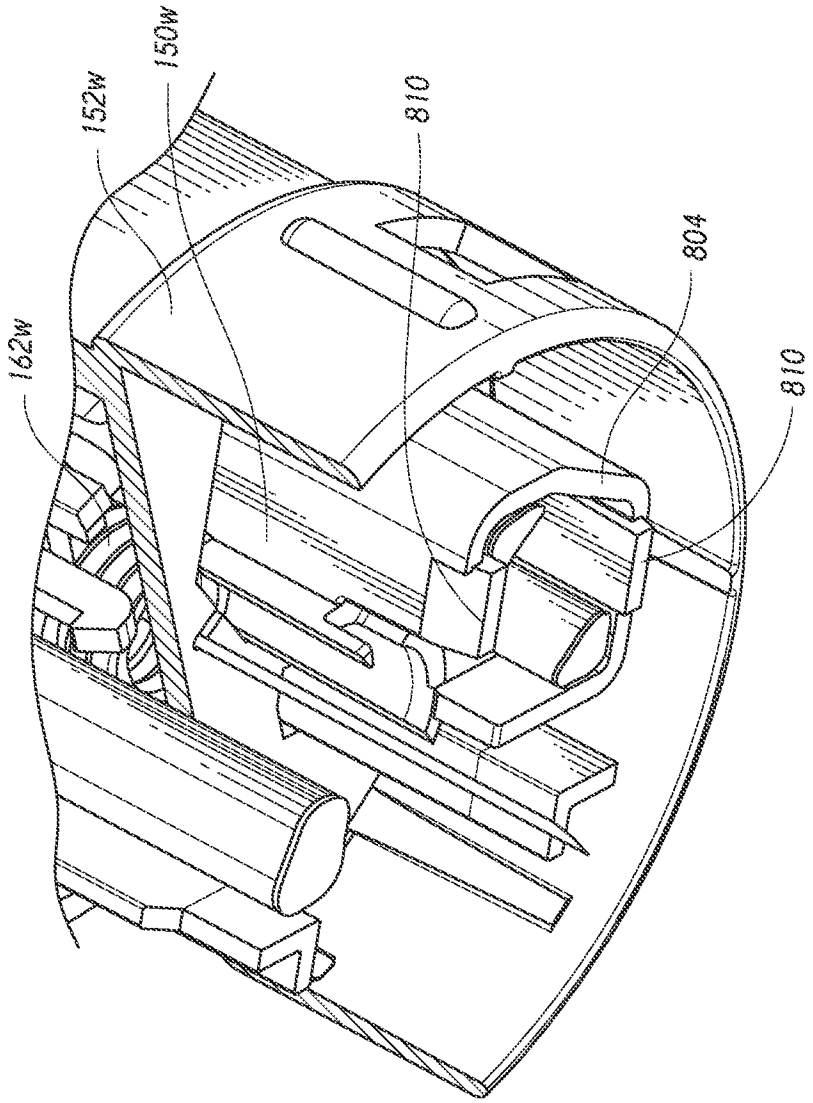


FIG. 117

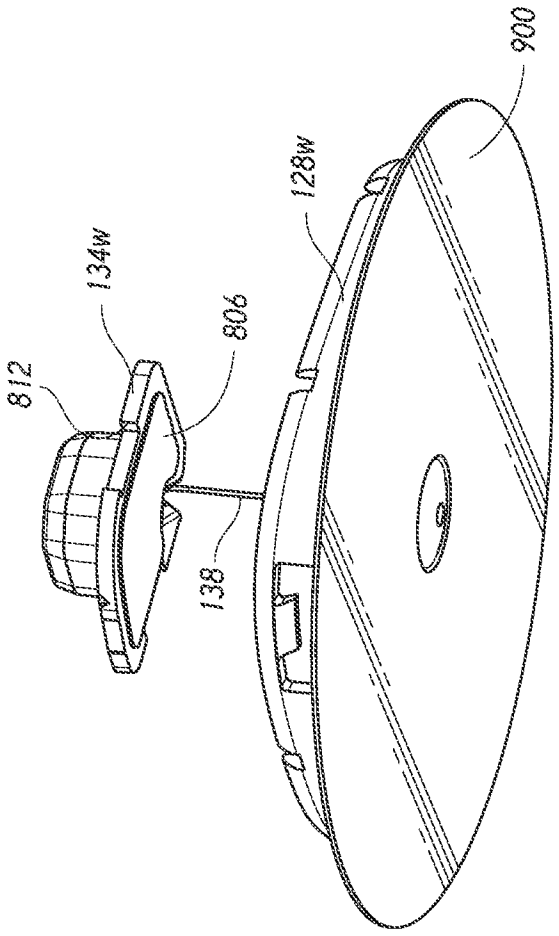


FIG. 118

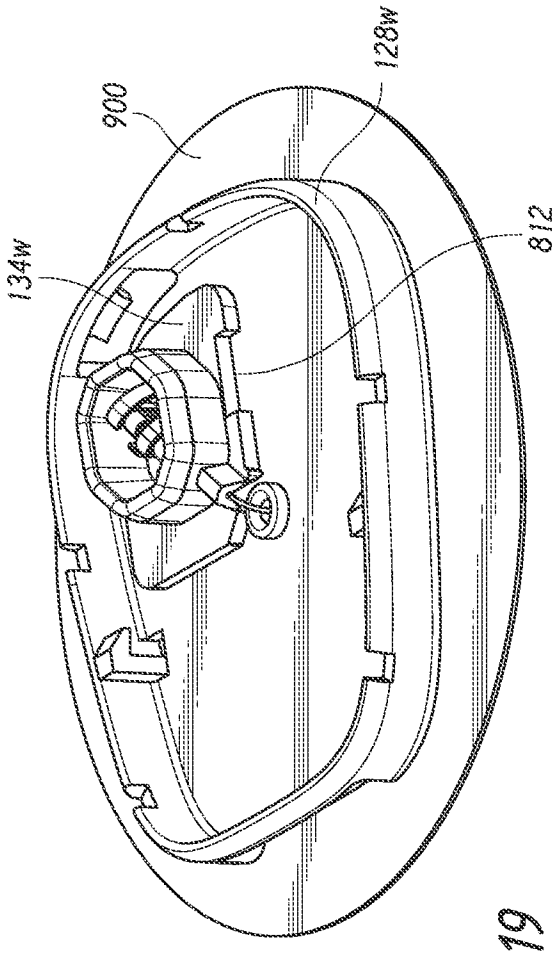


FIG. 119

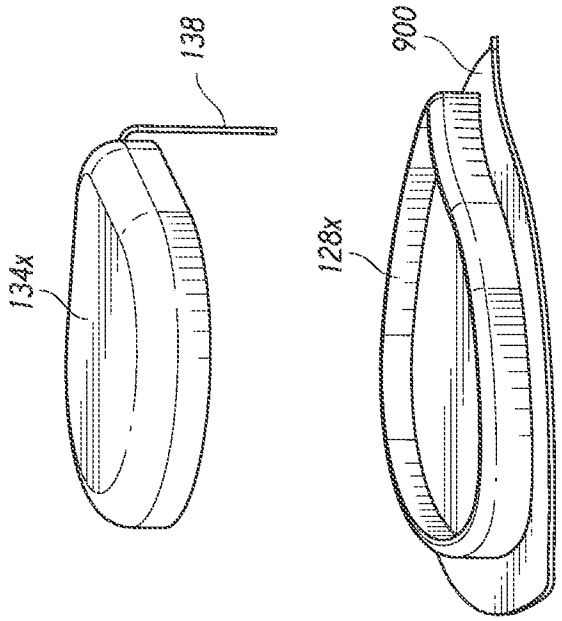
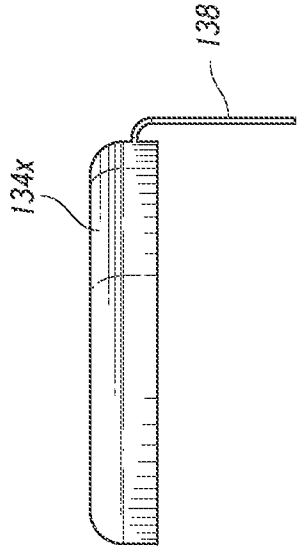


FIG. 121



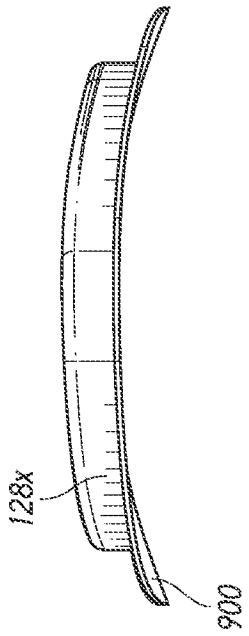


FIG. 120

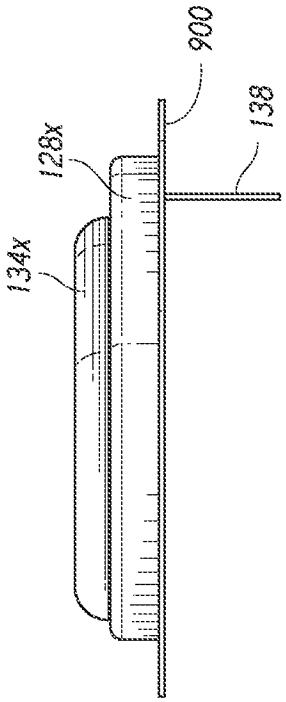


FIG. 122

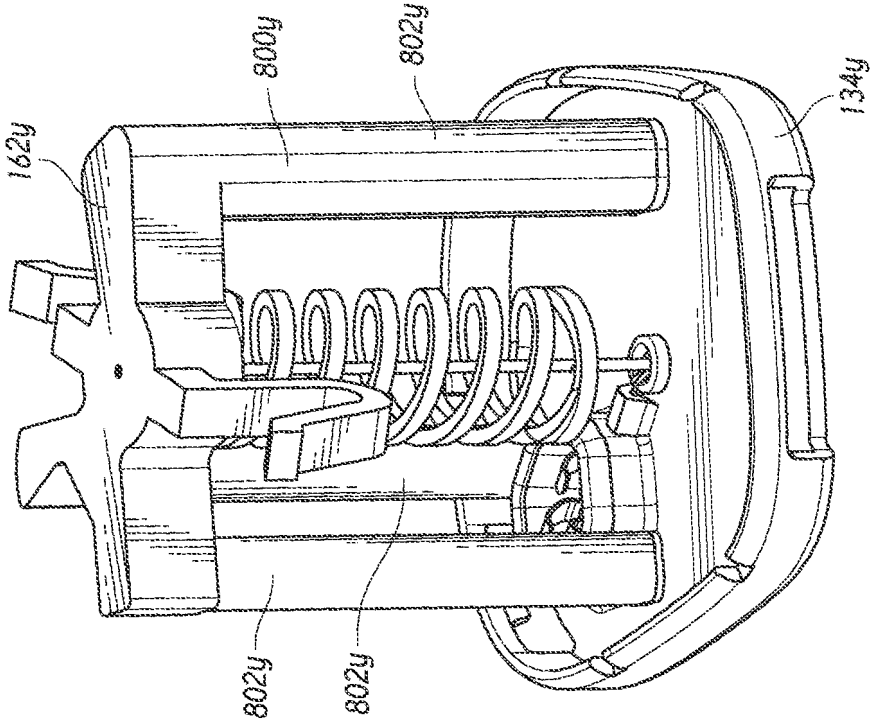


FIG. 124

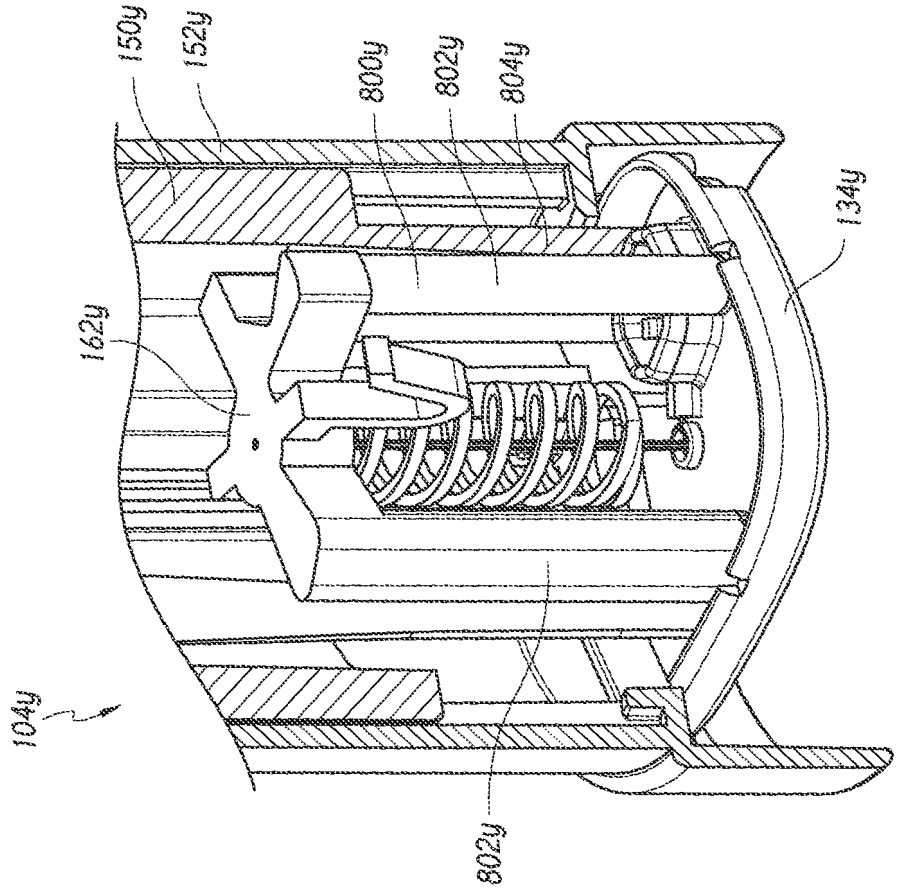


FIG. 123

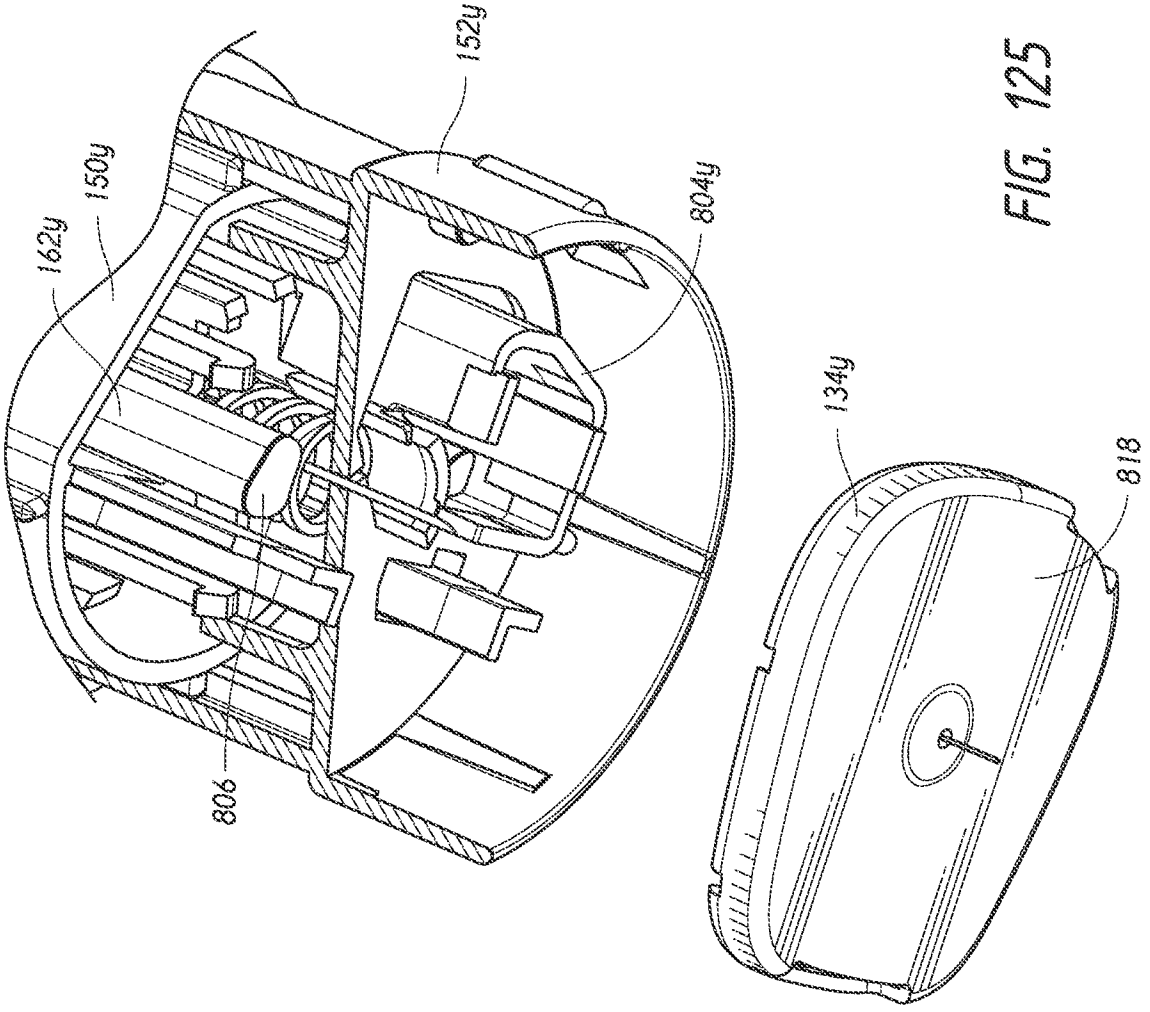


FIG. 125

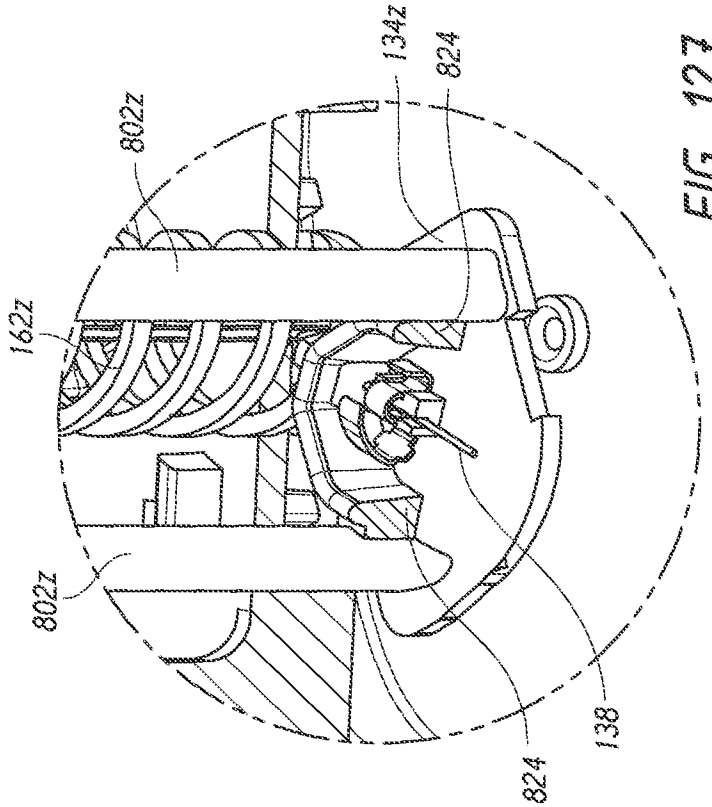


FIG. 127

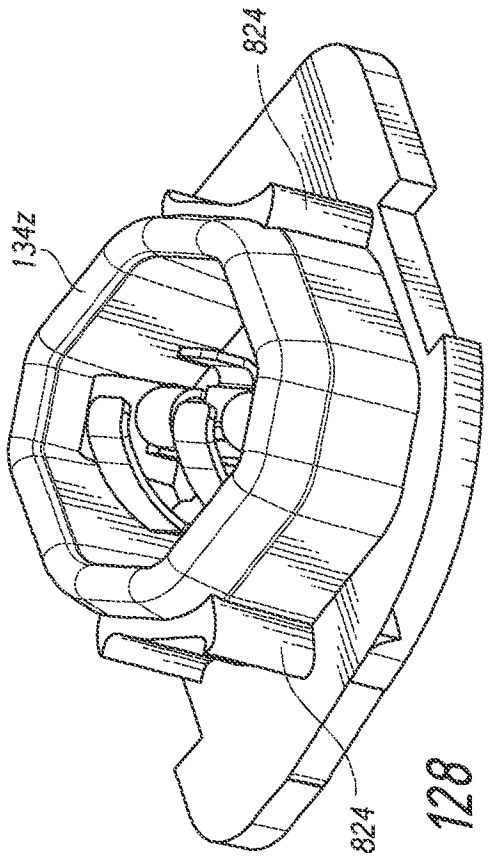


FIG. 128

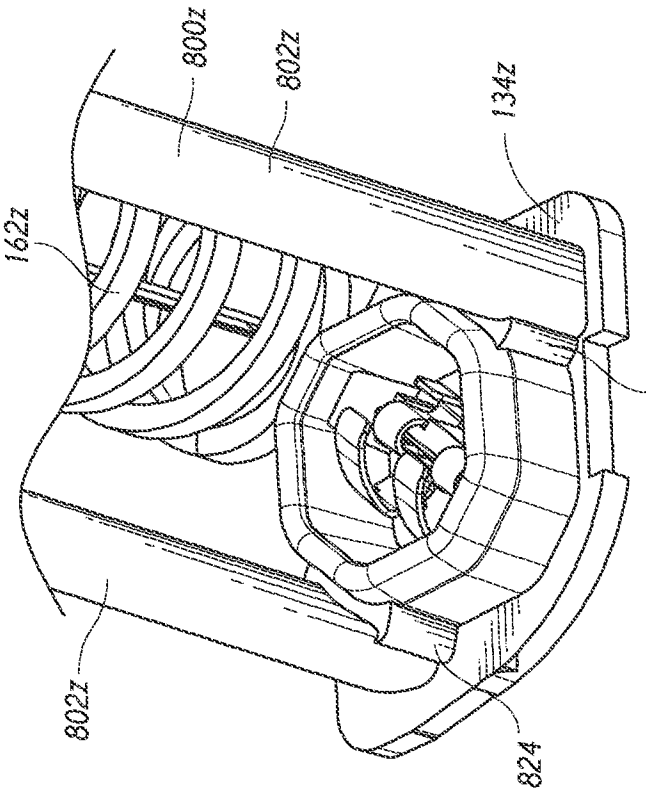
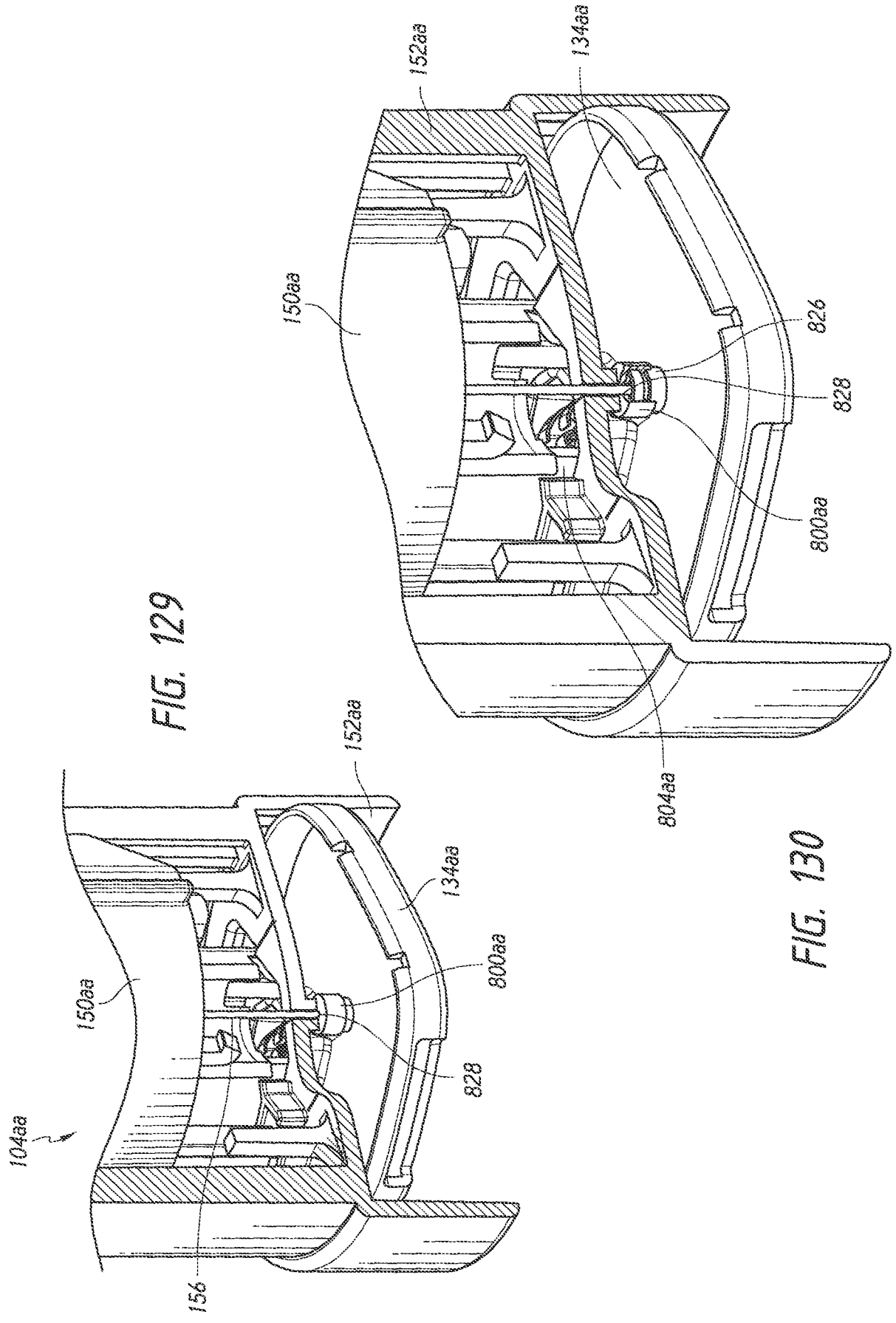


FIG. 126


104aa
150aa
152aa
134aa
800aa
828
156
FIG. 129
150aa
152aa
134aa
826
828
800aa
804aa
FIG. 130

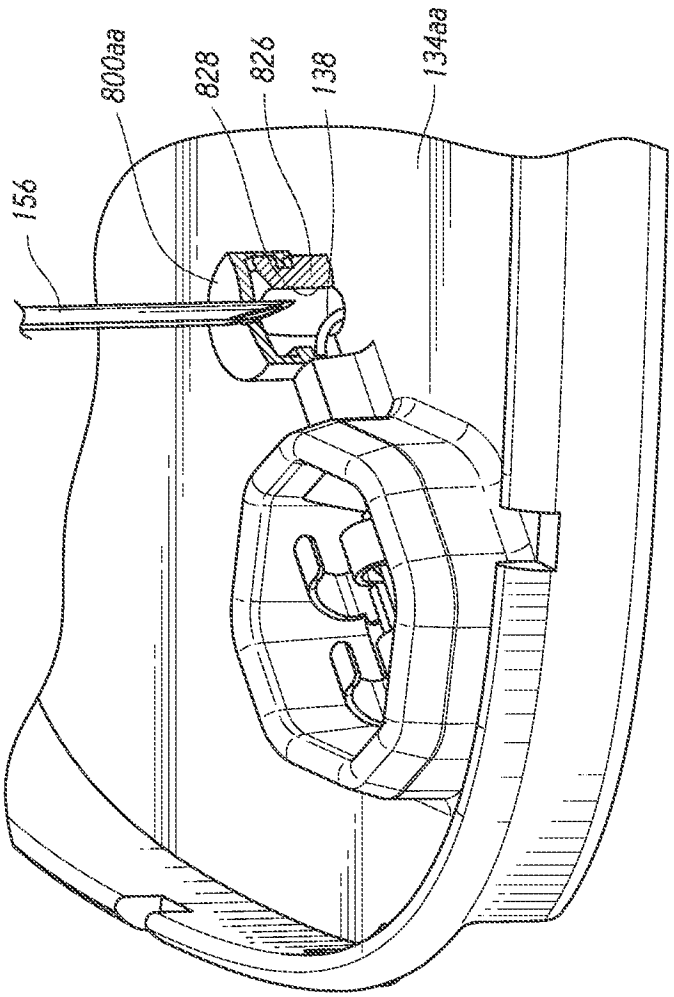


FIG. 131

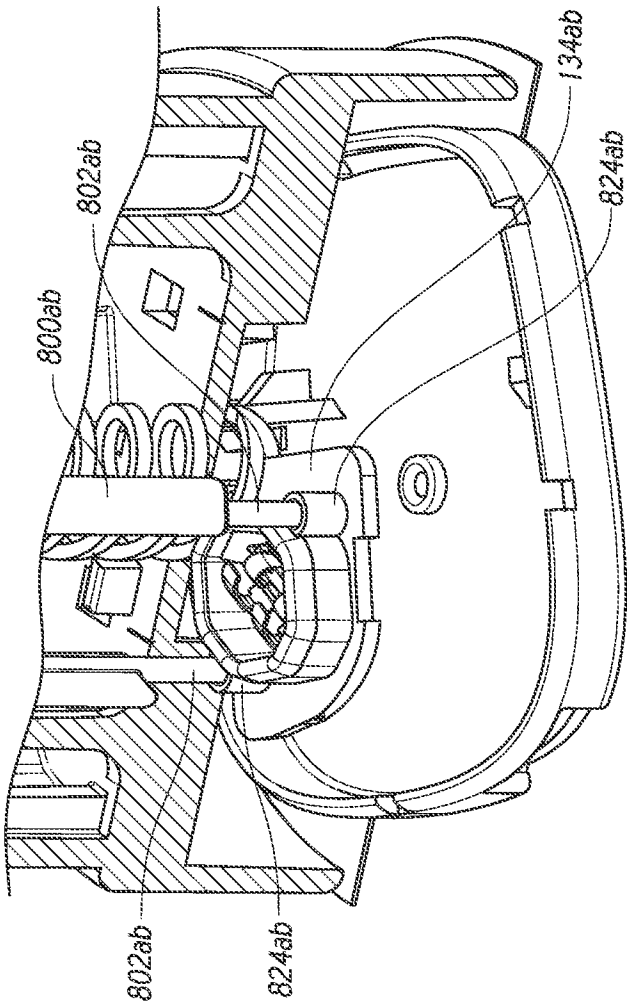


FIG. 132

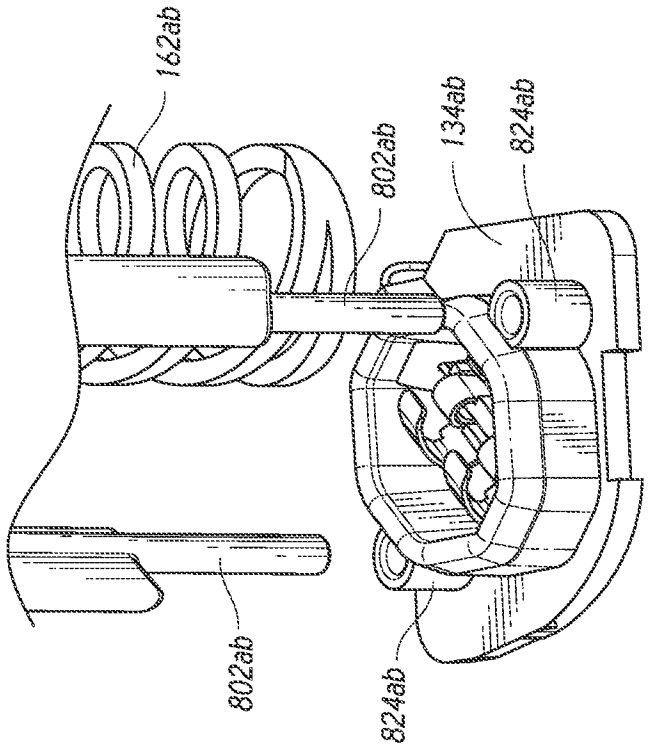


FIG. 133

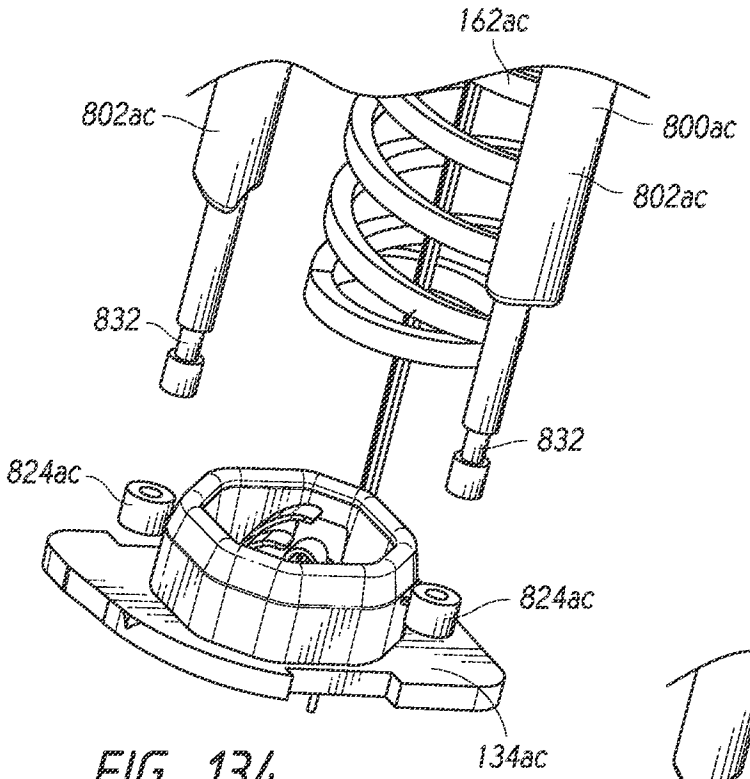


FIG. 134

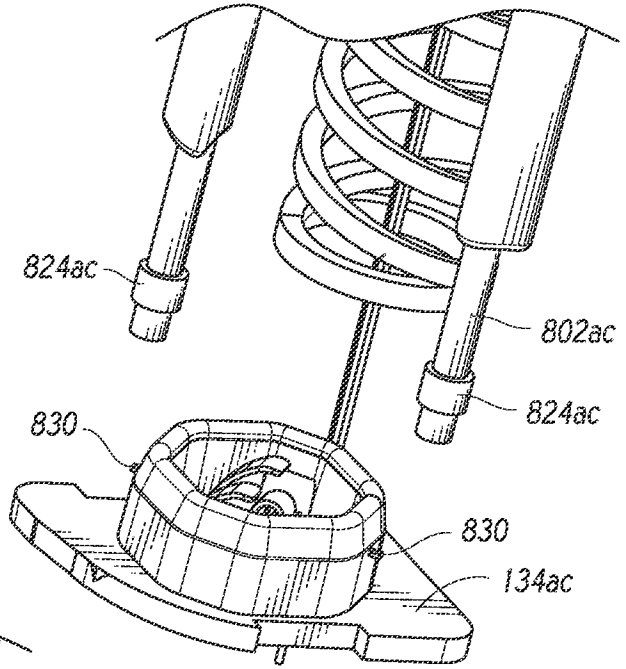


FIG. 136

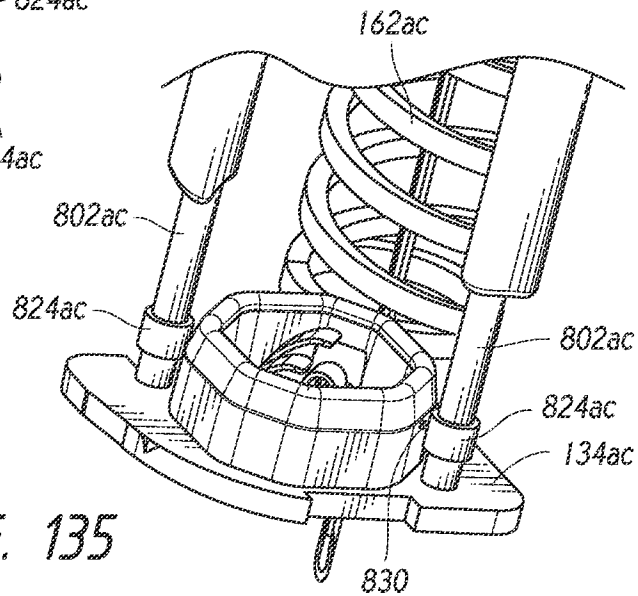


FIG. 135

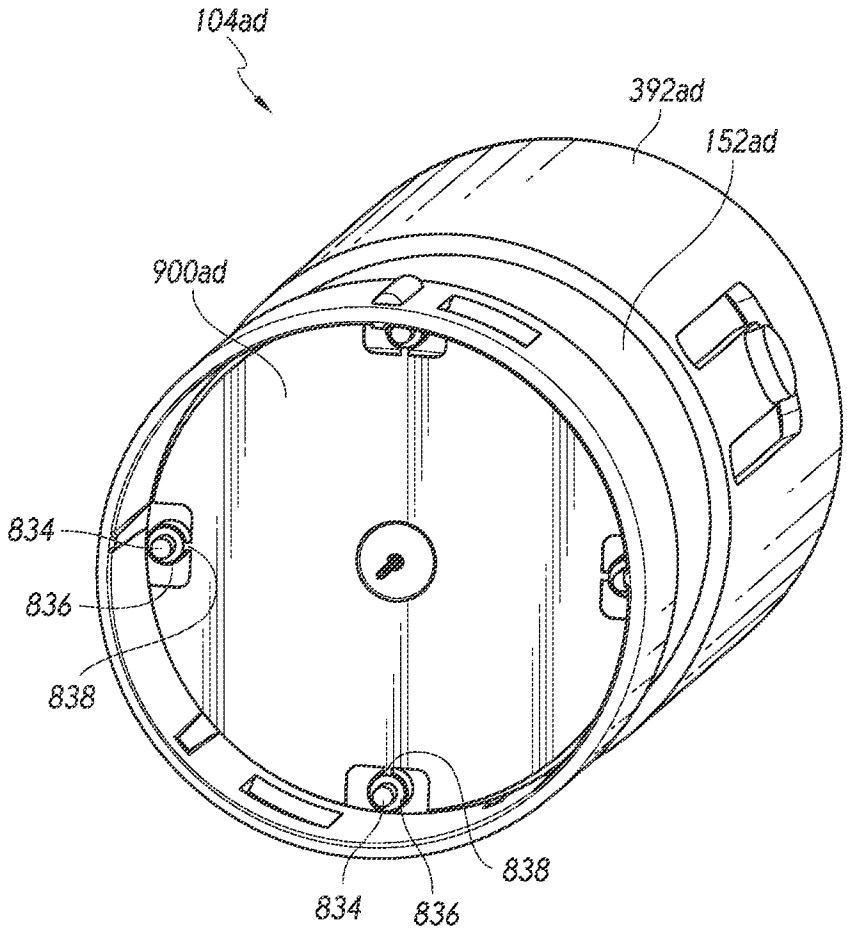


FIG. 137

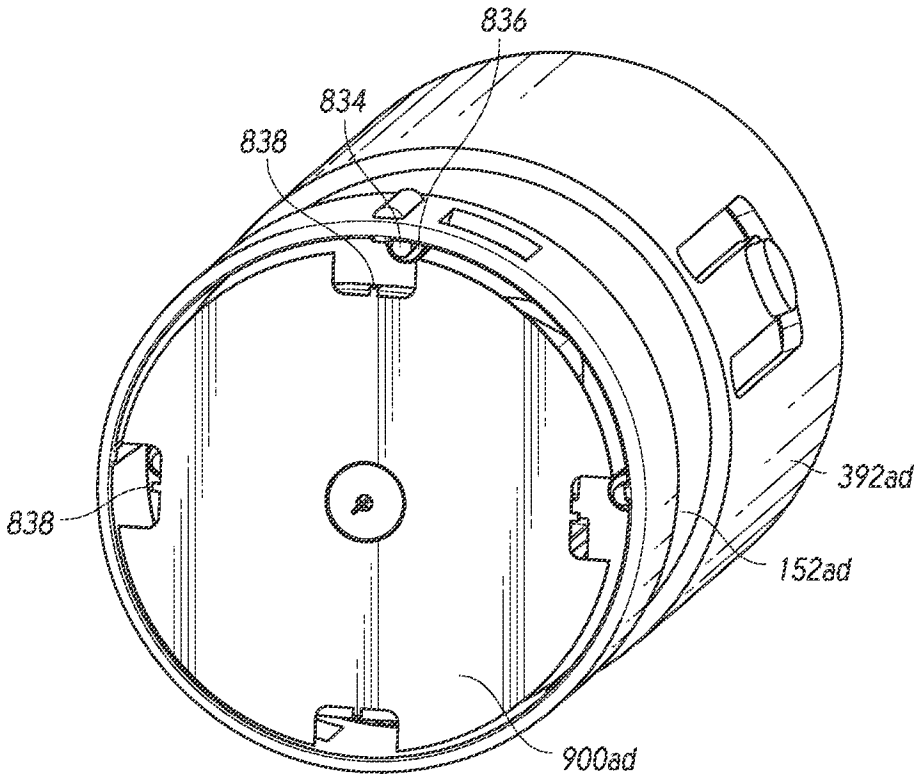


FIG. 138

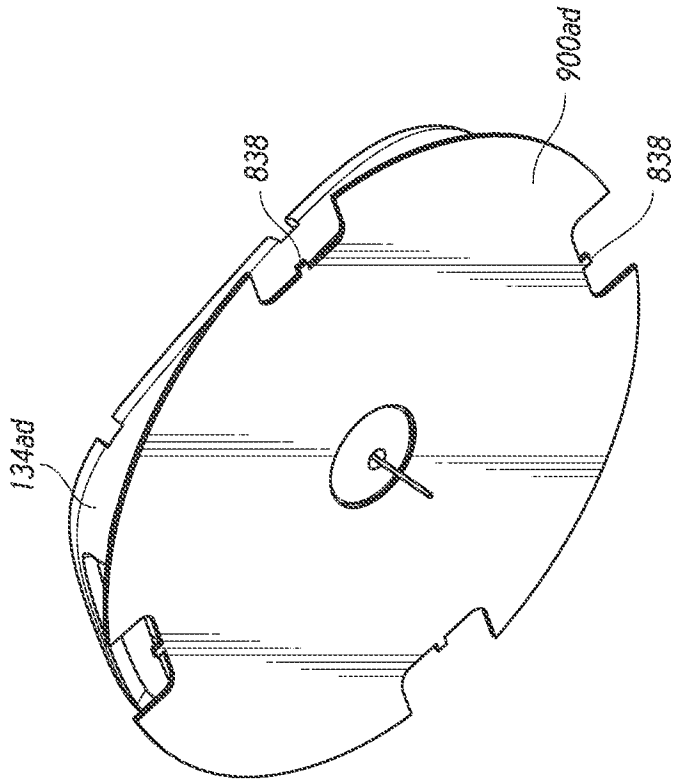


FIG. 140

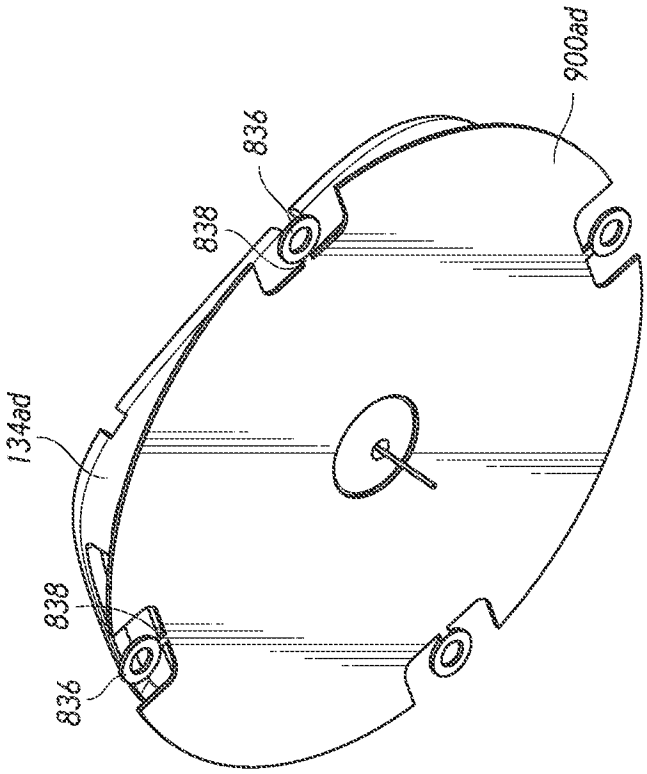


FIG. 139

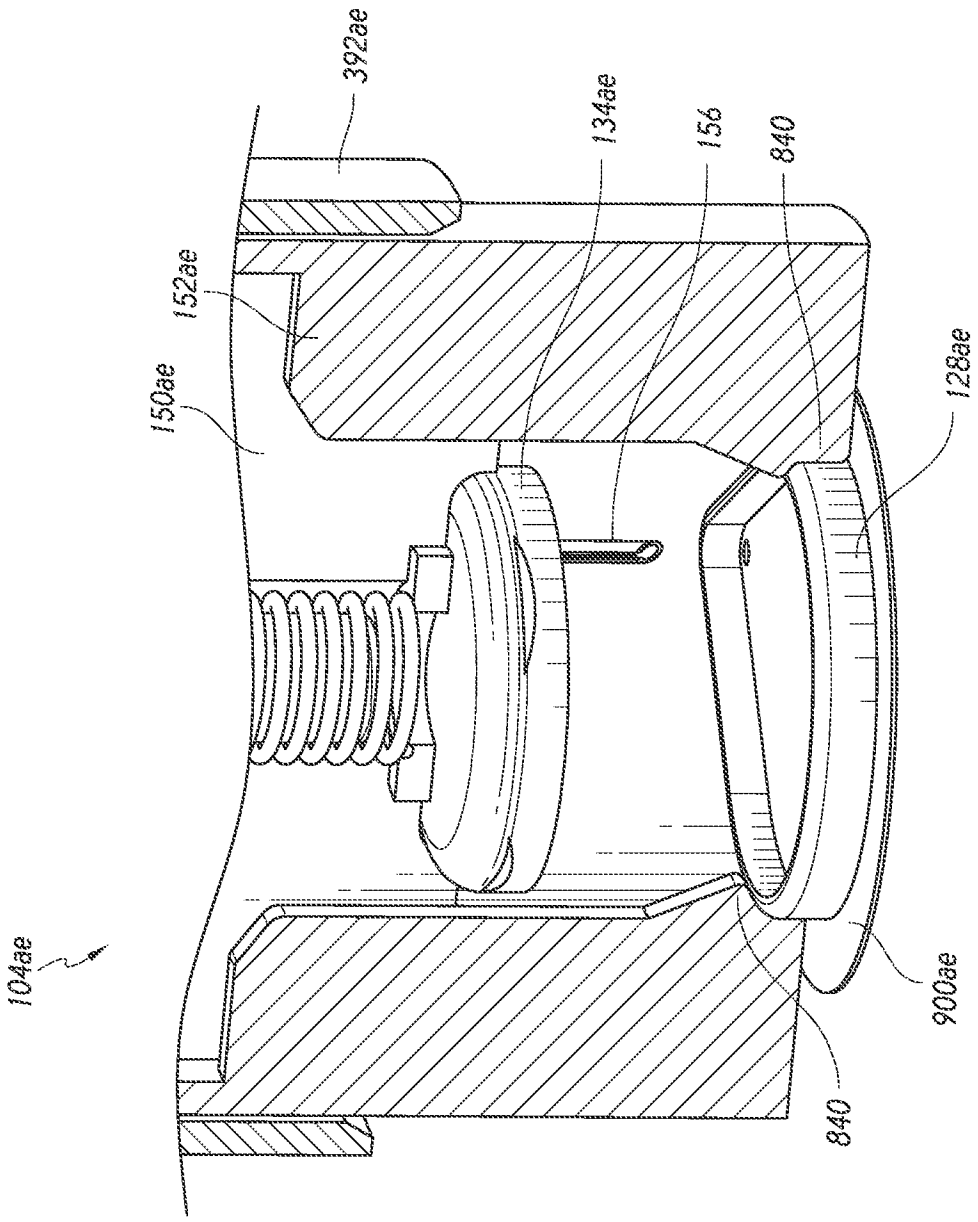


FIG. 141

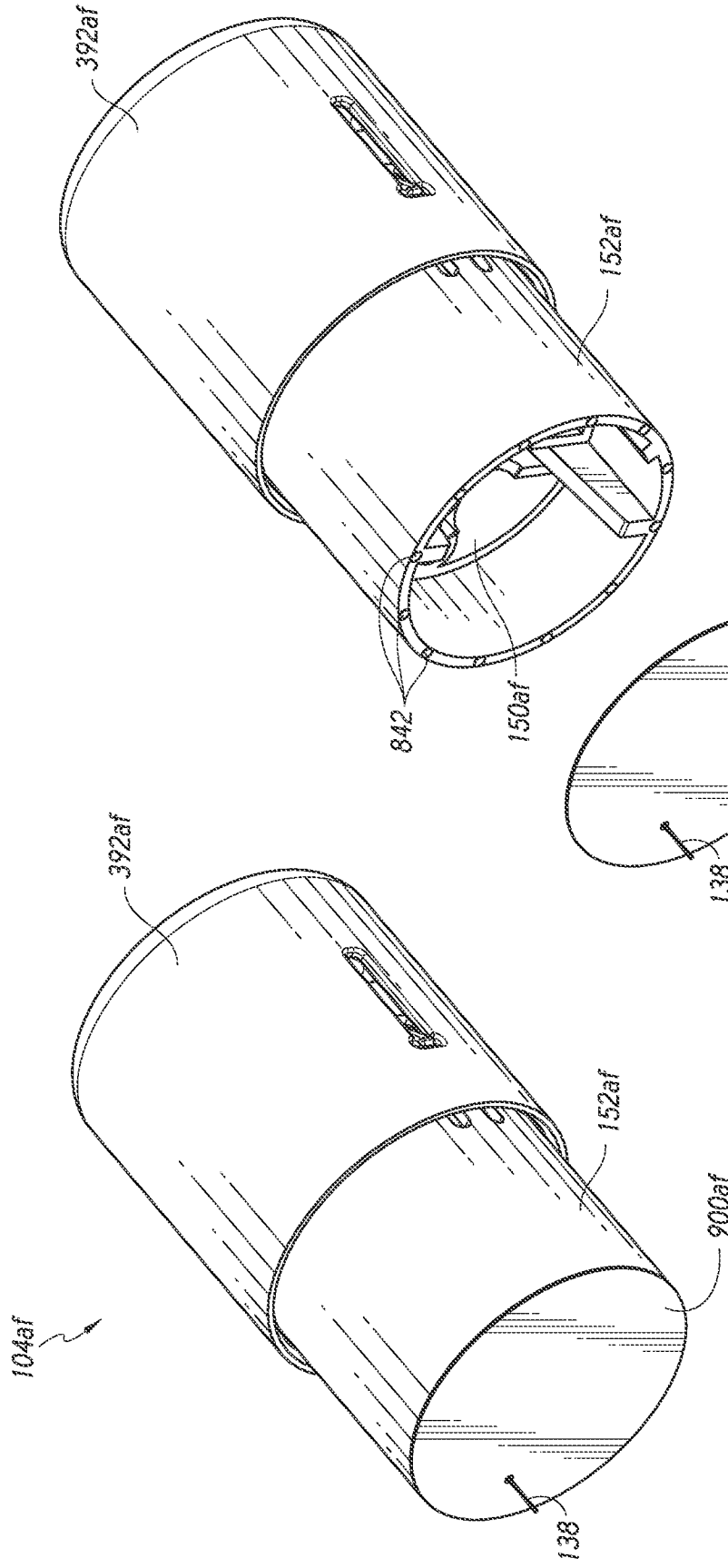


FIG. 142

FIG. 143

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

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Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	Michael	Gray	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Diego	CA	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive
City	San Diego
State/Province	CA
Postal Code	92121
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jennifer		Blackwell	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Diego	CA	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive
City	San Diego
State/Province	CA
Postal Code	92121
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Paul	V.	Neale	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

City	San Diego	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA
Postal Code	92121	Country	US

Inventor 4 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Justen	Deering	England	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Francisco	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA
Postal Code	92121	Country	US

Inventor 5 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew		Joncich	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Madison	State/Province	WI	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA
Postal Code	92121	Country	US

Inventor 6 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Cameron		Brock	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Francisco	State/Province	CA	Country of Residence	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 7 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Peter	C.	Simpson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Cardiff by the Sea	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 8 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Metzmaker	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 9 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Neel		Shah	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Carlsbad	**State/Province**	CA	**Country of Residence** i	US

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 10 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Mark	Douglas	Kempkey	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Vista	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 11 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Patrick	John	Castagna	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 12 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Warren		Terry	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Poway	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 13 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jason		Halac	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 14 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Christian	Michael Andre	George	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 15 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Daniel	E.	Apacible	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Chula Vista	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Address 2	6340 Sequence Drive		
City	San Diego	**State/Province**	CA
Postal Code	92121	**Country** i	US

Inventor 16 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John	Charles	Barry	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	**State/Province**	CA		
Postal Code	92121	**Country** i	US		

Inventor 17 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Joseph	J.	Baker	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Vista	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	**State/Province**	CA		
Postal Code	92121	**Country** i	US		

Inventor 18 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Philip	Thomas	Pupa	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	**State/Province**	CA	**Country of Residence** i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

Inventor 19 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Timothy	Joseph	Goldsmith	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

Inventor 20 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jon		Bodnar	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Keller	State/Province	TX	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

Inventor 21 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Neal	Davis	Johnston	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Dallas	State/Province	TX	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.
Address 2	6340 Sequence Drive

City	San Diego	State/Province	CA

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Postal Code	92121	Country i	US

Inventor 22 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Maria	Noel Brown	Wells	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

Inventor 23 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Kenneth		Pirondini	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Diego	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

Inventor 24 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Andrew	Michael	Reinhardt	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Santee	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	c/o DexCom, Inc.		
Address 2	6340 Sequence Drive		
City	San Diego	State/Province	CA
Postal Code	92121	Country i	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	68851		
Email Address	efiling@knobbe.com	Add Email	Remove Email

Application Information:

Title of the Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS		
Attorney Docket Number	DEXCOM.394PR	**Small Entity Status Claimed**	☐
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	69	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	68851		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor

● Person to whom the inventor is obligated to assign. | Person who shows sufficient proprietary interest

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	DexCom, Inc.		
Mailing Address Information For Applicant:			
Address 1	6340 Sequence Drive		
Address 2			
City	San Diego	**State/Province**	CA
Country	US	Postal Code	92121
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. OMB 0651-0032
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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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Rose M. Thiessen/			Date (YYYY-MM-DD)	2017-06-23
First Name	Rose M.	Last Name	Thiessen	Registration Number	40202

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	DEXCOM.394PR
	Application Number	
Title of Invention	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS	

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Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
First Named Inventor/Applicant Name:	John Michael Gray
Filer:	Rose M. Thiessen/Edgar Compton
Attorney Docket Number:	DEXCOM.394PR

Filed as Large Entity

Filing Fees for Provisional

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
PROVISIONAL APPLICATION FILING	1005	1	260	260
Pages:				
PROV. APPL SIZE FEE PER 50 SHEETS >100	1085	6	400	2400
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**2660**

Electronic Acknowledgement Receipt

EFS ID:	29591566
Application Number:	62524247
International Application Number:	
Confirmation Number:	9556
Title of Invention:	TRANSCUTANEOUS ANALYTE SENSORS, APPLICATORS THEREFOR, AND ASSOCIATED METHODS
First Named Inventor/Applicant Name:	John Michael Gray
Customer Number:	68851
Filer:	Rose M. Thiessen/Sandra Autry
Filer Authorized By:	Rose M. Thiessen
Attorney Docket Number:	DEXCOM.394PR
Receipt Date:	23-JUN-2017
Filing Date:	
Time Stamp:	17:10:00
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$2660
RAM confirmation Number	062617INTEFSW17111100
Deposit Account	111410
Authorized User	Sandra Autry

The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:

37 CFR 1.16 (National application filing, search, and examination fees)

37 CFR 1.17 (Patent application and reexamination processing fees)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Drawings-only black and white line drawings	394PR_DRAW.pdf	934699 b625eb87cd116ff29b81e67d6c8d57286e5a4af6	no	69
Warnings:					
Information:					
2	Specification	394PR_SPEC.pdf	16424941 6f8cbfe8d60dbc6ad91086140e8d325aafcc0311	no	412
Warnings:					
Information:					
3	Application Data Sheet	394PR_ADS_v2.pdf	1824240 f39659f813e02d3ab3abeedf547babd85603c799	no	15
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	31914 b9230a8f71661c6afe034cb71366e8417e0e8fd8	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	19215794		

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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

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New International Application Filed with the USPTO as a Receiving Office

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