

LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS

Technical Field

[0001] The present invention relates generally to the field of medical devices, and more particularly to lancets and lancing devices for blood sampling and testing.

Background of the Invention

[0002] Lancets and lancing devices are utilized for penetrating the skin of a human or animal subject at a lancing site to obtain a sample of blood or other body fluid for medical testing, as in blood-typing or blood-glucose testing. Known lancing devices commonly include a housing containing a drive mechanism, a charging mechanism for energizing the spring or other drive means of the drive mechanism, and a release mechanism for releasing the drive mechanism upon actuation. A lancet is typically propelled by the drive mechanism from a retracted position shielded within the housing to an extended position wherein a sharp tip portion of the lancet projects from the housing to prick the subject's skin at a desired lancing site. An ejection mechanism can optionally be included for discharge of a used lancet from the lancing device.

[0003] The lancet is typically a disposable component that is removably mounted into a receiver or lancet carrier portion of the drive mechanism of a lancing device. A used lancet typically is removed from the lancet carrier after sampling for disposal. A new, sterile lancet is then replaced into the lancet carrier for further sampling. Lancets typically comprise a sharp metal tip in the form of a needle or blade. The needle or blade is typically embedded in a plastic body that has a size and shape configured for releasable engagement with the receiver or lancet carrier of a lancing device. The sharp tip of the lancet is commonly embedded in a removable plastic cap to maintain sterility and prevent

inadvertent sticks prior to use. The endcap may be replaceable onto the lancet after use to re-cover the sharp lancet tip for safety and hygienic purposes.

[0004] It is to the provision of improved lancets that the present invention is primarily directed.

Summary of the Invention

[0005] In example embodiments, the present invention provides improved lancet designs with various advantages over previously known lancets.

[0006] In one aspect, the present invention is a lancet having one or more cantilevers or resilient coupling members, such as arms, fingers, barbs, flared portions, projections, or the like on the lancet body, for engagement with a cooperating coupling member of a lancing device, facilitating ease of insertion and ejection in use.

[0007] In another aspect, the present invention is a lancet having a sterility cap or protective cover with a handle for assisting in removal of the cap for use of the lancet and/or for replacement of the cap onto a used lancet for disposal.

[0008] In still another aspect, the present invention is a sterility cap or protective cover for a lancet, the cap or cover having a handle for assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal.

[0009] In another aspect, the present invention is a lancet having a lancet body with a smoothly curved side profile, having at least one crest and at least one trough for engagement with cooperating coupling portions of a lancing device. An expanded disc or flange optionally projects from the lancet body to assist in ejection and removal of the lancet.

[0010] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will

be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[0011] FIGURES 1a – 1d show example embodiments of a lancet having cantilevers or resilient coupling members on the lancet body.

[0012] FIGURES 2a – 2c show example embodiments of a protective sterility cap for a lancet, according to the present invention.

[0013] FIGURES 3a – 3c show example embodiments of a lancet having a smoothly curved lancet body contour.

Detailed Description of Example Embodiments

[0014] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Any and all patents and other publications identified in this specification are incorporated by reference as though fully set forth herein.

[0015] Also, as used in the specification including the appended claims, the singular forms “a,” “an,” and “the” include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise.

Ranges may be expressed herein as from “about” or “approximately” one particular value and/or to “about” or “approximately” another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, such as by use of the antecedent “approximately” or “about,” it will be understood that the particular value forms another embodiment.

[0016] With reference now to the drawing figures, **FIGURES 1a – 1d** show example embodiments of lancets according to the present invention, and having one or more cantilevers or resilient coupling members, such as arms, fingers, barbs, flared portions, projections, or the like on the lancet body, for engagement with a cooperating coupling member or receiver of a lancing device, facilitating ease of insertion and ejection in use. There are 4 variations labeled 1a-1d, respectively. The lancets of each variation incorporate one or more cantilevers on the lancet body to interface with the lancing device. This allows for a snap fit coupling or connection between the lancet and the device. One or more of the following advantages/functions may be provided by example embodiments of the cantilever lancet:

1. The cantilevers retain the lancet in the device. Positive snaps hold the lancet in place better than existing lancets.
2. A ring is optionally formed around the front of the lancet body to provide a better user interface for lancet removal if there is not an ejection feature on the lancing device.
3. The cantilevers provide an interface between the lancet and the lancing device for ejection.
4. The shape of the lancet provides a guiding feature for the user to insert the lancet into the lancing device.
5. Lancet insertion and ejection forces are easily adjusted on the lancing device through changing the interaction between the cantilevers and the lancet holder.

6. Lancets look more “friendly and painless.”
7. Lancets are tapered for easy insertion into the device.
8. Cantilevers are naturally tolerance absorbing, allowing for better guidance of the lancet and for tighter tolerances in the mating parts.
9. Design limits the rotation of the lancet inside of the lancet holder.
10. Shorter lancet ejection stroke.
11. Tapered shape aids in ejection.
12. On designs with more than 2 cantilevers the front ones can be larger than the back ones so that the ejection stroke remains short.
13. Simplified lancet holder design. Does not have to accommodate different brands/sizes/types of lancets from different manufacturers.
14. Chances of partial lancet insertion are reduced since the lancets will click/snap into position, notifying the user of complete insertion.

[0017] **Figures 2a - 2c** show example protective / sterility caps for a lancet, according to the present invention. The cap or cover includes a “handle” or extension arm for assisting in removal of the cap from the lancet, and/or for replacement of the cap onto a used lancet for disposal. The handles allow for the body of the lancet to be smaller than a Regular Version (RV) lancet, allowing the corresponding lancing devices to be smaller. The sterility caps optionally have one or more readily visible circular or flat areas that are used for applying branding/logos, and are positioned so that the user can replace the cap by inserting the exposed sharp of the lancet therein before disposal. The wide ring at the base of the lancet sterility cap interfaces with the lancet body to allow for the user to twist the cap off of the body without damaging the tip of the exposed needle. The invention also includes lancets having such a protective cap. One or more of the following advantages/functions may be provided by example embodiments of the lancet cap:

1. Allows the user's hands to grab the "sterility handle" further from the needle while decapping and use with a used lancet. This allows a larger safety margin from the needle tip, protecting the patient and other persons handling the lancet.
2. Large size for people with limited dexterity and/or poor vision.
3. Larger cap allows the lancet body to be reduced in size since the lancet can be handled by the sterility cap prior to insertion.
4. Intuitive to grab the handle end of the sterility cap.
5. Patients will not lose or drop the sterility tab as easily since it is larger.
6. The lancet is easy to pick up off of a flat surface such as a table or countertop.
7. The disc at the base of the sterility handle can be used for lancet insertion, providing a hard stop for consistent placement.
8. Safer for patients, healthcare professionals, diabetes educators, and others who handle lancets.

[0018] In the embodiment of **Figure 2c**, the center area of the lancet cap handle is filled with plastic, rather than being an open loop, so that the lancets do not get tangled during shipping and normal use.

[0019] Figures 3a – 3c show example lancets according to another form of the invention. These lancets include a lancet body that allows for the lancet to be inserted into the device and snapped into position. The wavy design of the lancet body is shaped so that it snaps into engagement with a cooperating coupling of the lancing device at the narrower sections of the lancet body and/or fits snugly at its widest sections and is easy to eject due to the smooth curves and transitions on the lancet body. The lancet body can be formed of a resilient material and/or the receiver of the lancing device can comprise a resilient coupling for releasable engagement therebetween. The lancet body design also is curvy and appealing to the user, preferably having a smoothly contoured outer lancet body profile, without sharp corners, thereby reducing the appearance or perception to the user of

being a lancet that causes pain. One or more of the following advantages/functions may be provided by example embodiments of these lancets:

1. Less intimidating to the user. Smooth shape provides positive tactile feedback. The shape does not have any sharp edges to remind the user of a regular lancet.
2. Curved design is easy to pick up off of many different surfaces. The disc at the front of the lancet allows for easier grip for manual removal from the device, and the disc is the mating surface / connection point for the sterility cap
3. Troughs on the lancet body allow for attachment areas that interact with the lancing device to hold the lancet in place.
4. Crests on the lancet body allow for press fit/friction fit of the lancet into the lancing device.
5. The attachment points on the lancet allow for shorter ejection strokes
6. The flat disc at the front of the lancet can be used for ejection.
7. The flat shape of the lancet prevents it from rotating in the device.

[0020] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

What is Claimed is:

1. A lancet comprising a lancet body, a sharp lancing tip projecting from an end of the lancet body, and further comprising one or more resilient cantilevers or coupling members extending from said lancet body for engagement with a cooperating coupling member of a lancing device.
2. The lancet of Claim 1, wherein the resilient cantilevers comprise one or more fingers having a first end connected to the lancet body and a second free end distal from the lancet body.
3. The lancet of Claim 1, wherein the resilient cantilevers comprise one or more flexing bows having first and second ends connected to the lancet body and medial portions between the first and second ends separated a distance from the lancet body to define an opening therebetween.
4. The lancet of Claim 3, wherein the opening is substantially D-shaped.
5. The lancet of Claim 3, wherein the medial portion comprises a knob projecting away from the lancet body at its outermost extent.
6. The lancet of Claim 3, comprising first and second pairs of flexing bows, with a forward pair of bows being larger than a rearward pair of bows.
7. A protective sterility cap for a lancet, said sterility cap comprising a receiving portion for initial embedment of a sharp lancing tip of an unused lancet therein, and a gripping handle portion extending from the receiving portion.
8. The protective sterility cap of Claim 7, in combination with a lancet.
9. The protective sterility cap of Claim 7, further comprising a replacement shroud portion for receiving the sharp lancing tip of a used lancet.
10. The protective sterility cap of Claim 9, wherein the replacement shroud is affixed to the gripping handle opposite the receiving portion.

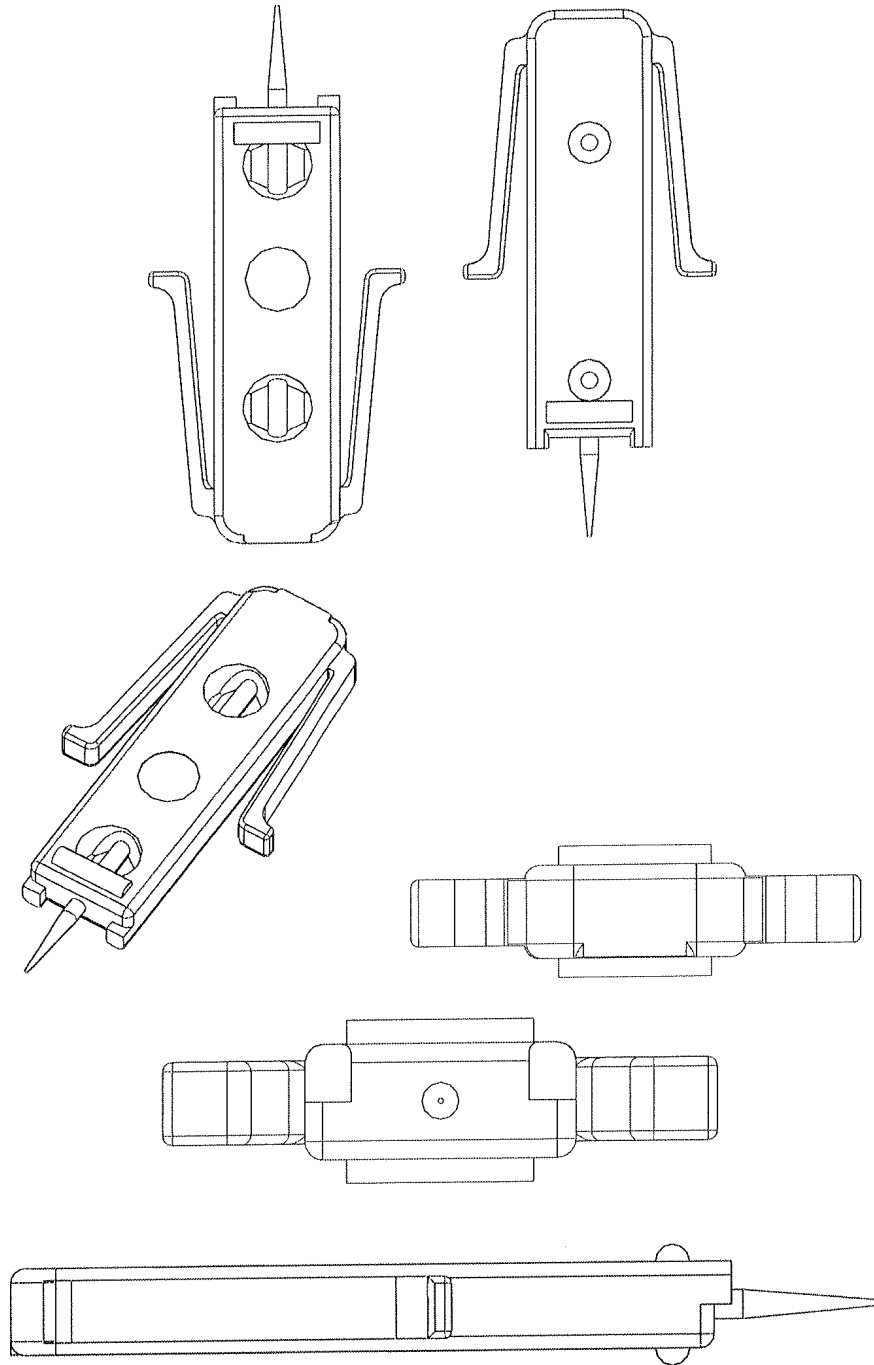
11. The protective sterility cap of Claim 7, further comprising at least one flat display surface for placement of branding indicia thereon.
12. The protective sterility cap of Claim 7, wherein the gripping handle portion comprises at least one open loop.
13. The protective sterility cap of Claim 7, wherein the gripping handle portion comprises a solid body without an open loop.
14. A lancet having a lancet body with a sharp lancing tip projecting from an end thereof, said lancet body comprising opposed first and second sides each defining a smoothly curved wave contour with a trough and a crest.
15. The lancet of Claim 14, further comprising an expanded disc or flange at an end of the lancet body.
16. The lancet of Claim 14, wherein the lancet body is flattened, having a width and a thickness, and wherein the width is substantially greater than the thickness.
17. The lancet of Claim 16, wherein an aspect ratio of the width relative to the thickness is at least 3:2.

ABSTRACT

Improved lancet configurations and protective lancet endcap configurations are disclosed. In example forms, one or more flexing cantilevers project from the lancet body for coupling with a cooperating receiver of a lancing device. A gripping handle extends from a sterility cap for ease of removal from and replacement over the lancet tip. A lancet body has a smoothly curved wave contour with at least one crest and at least one trough for engagement with a cooperating receiver of a lancing device.

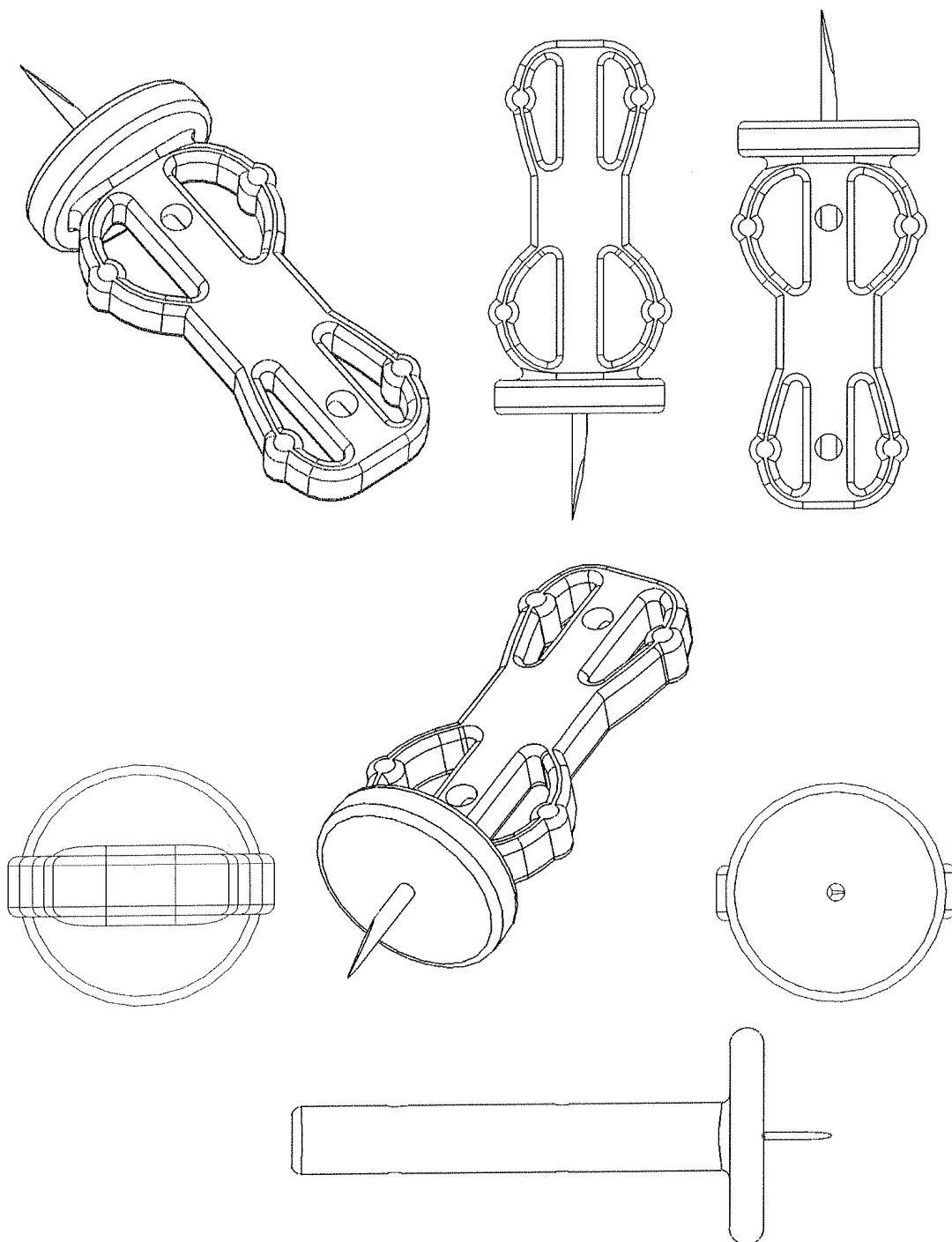
1/8

Figure 1a



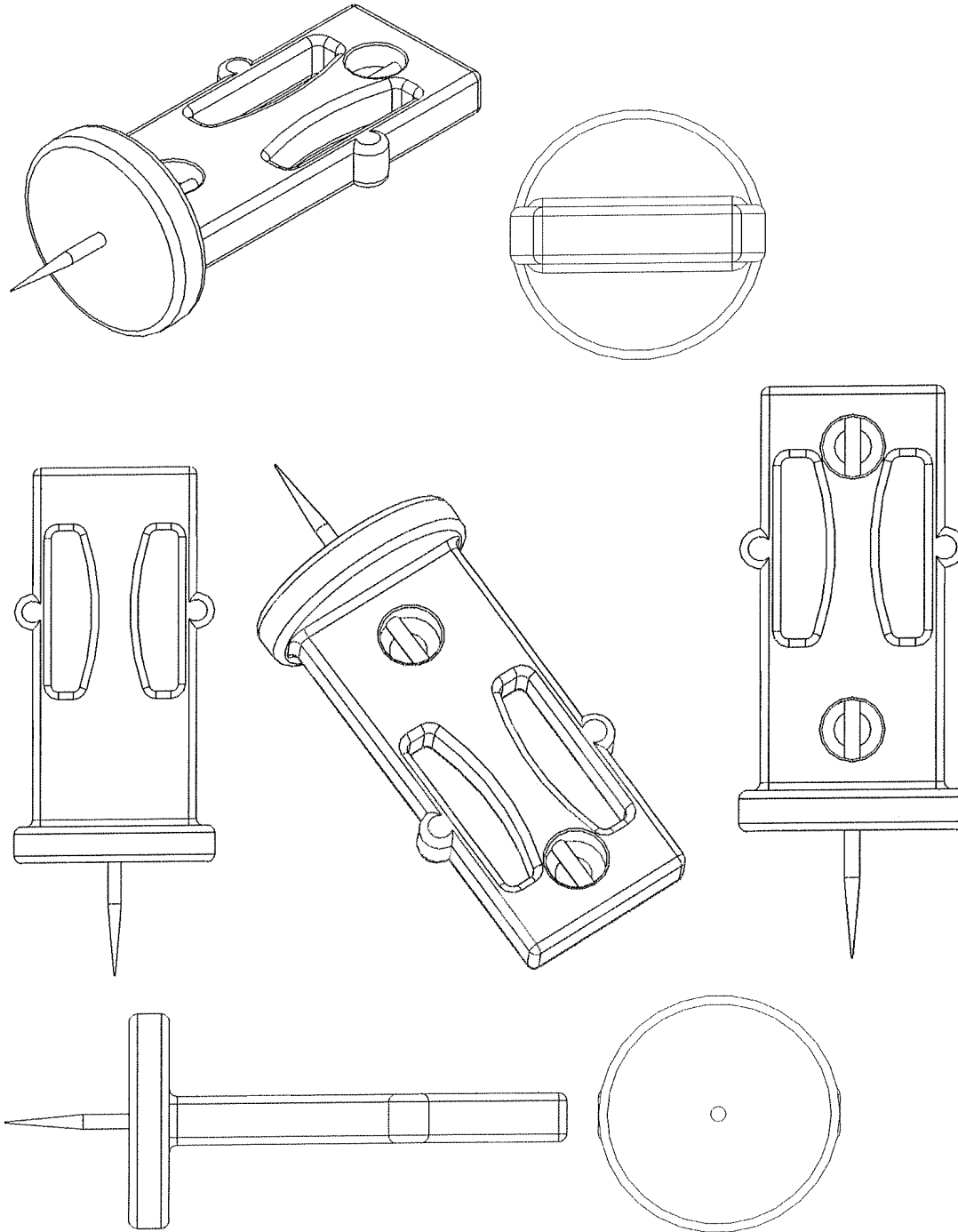
2/8

Figure 1b



3/8

Figure 1c



4/8

Figure 1d

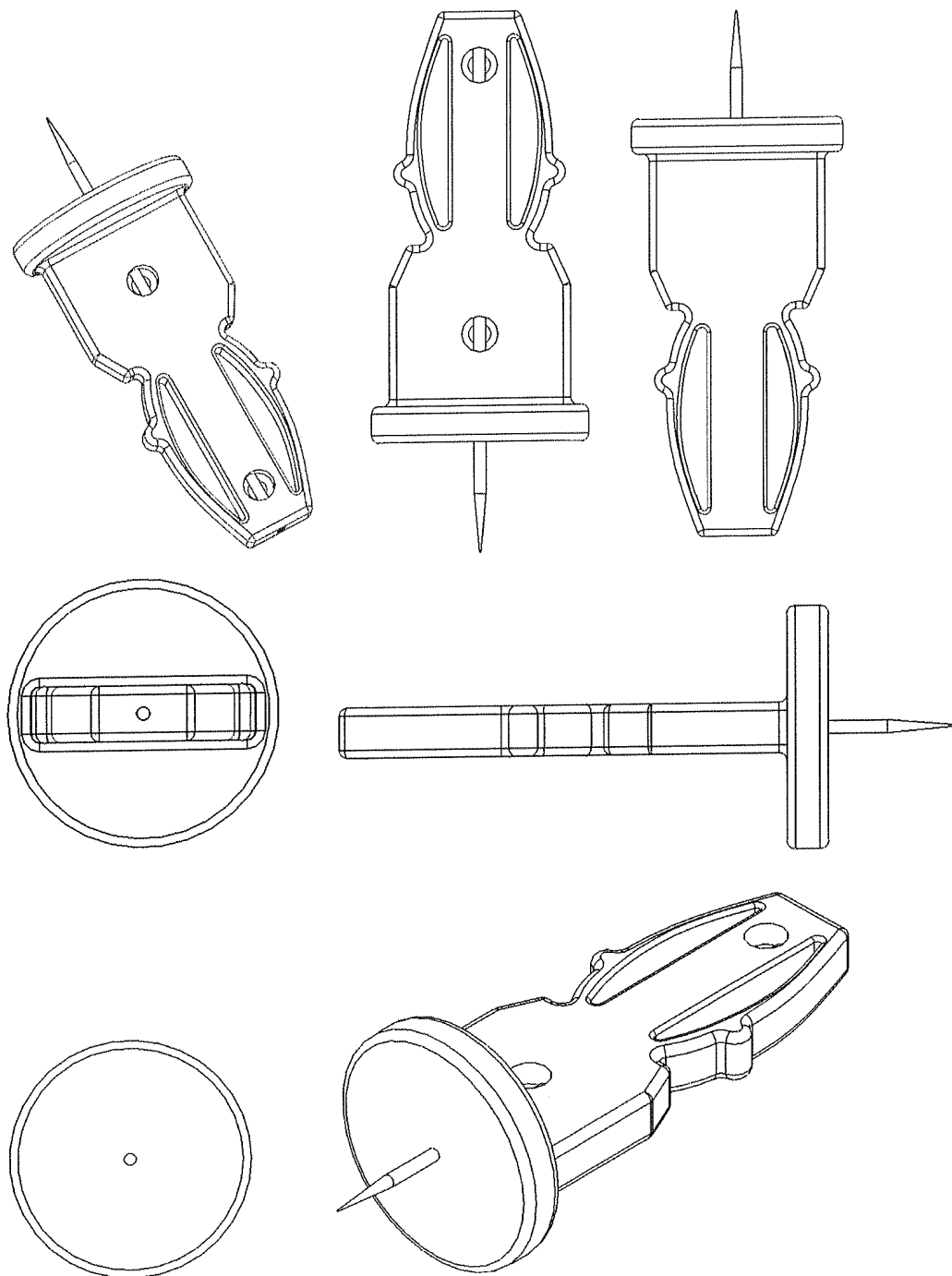
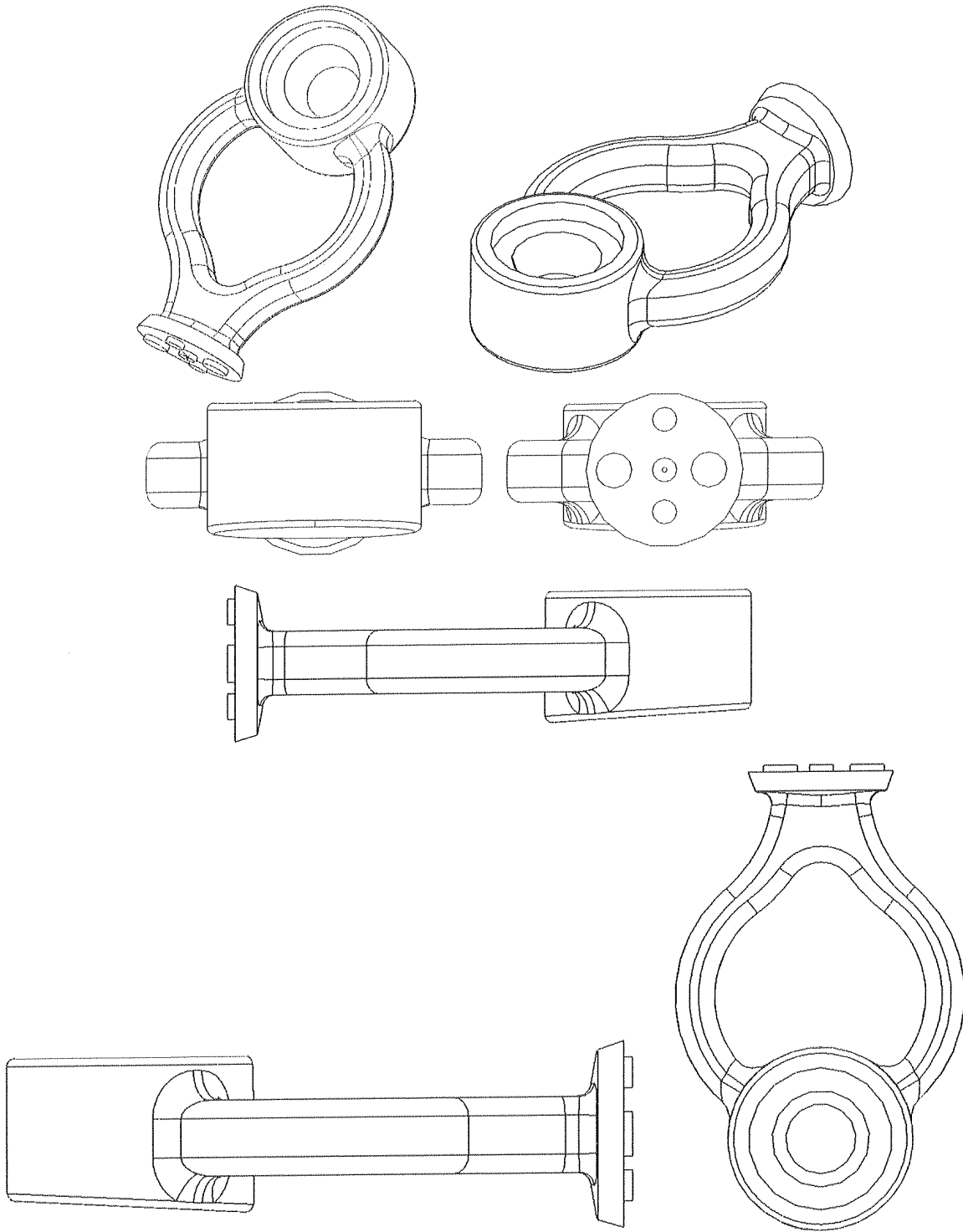
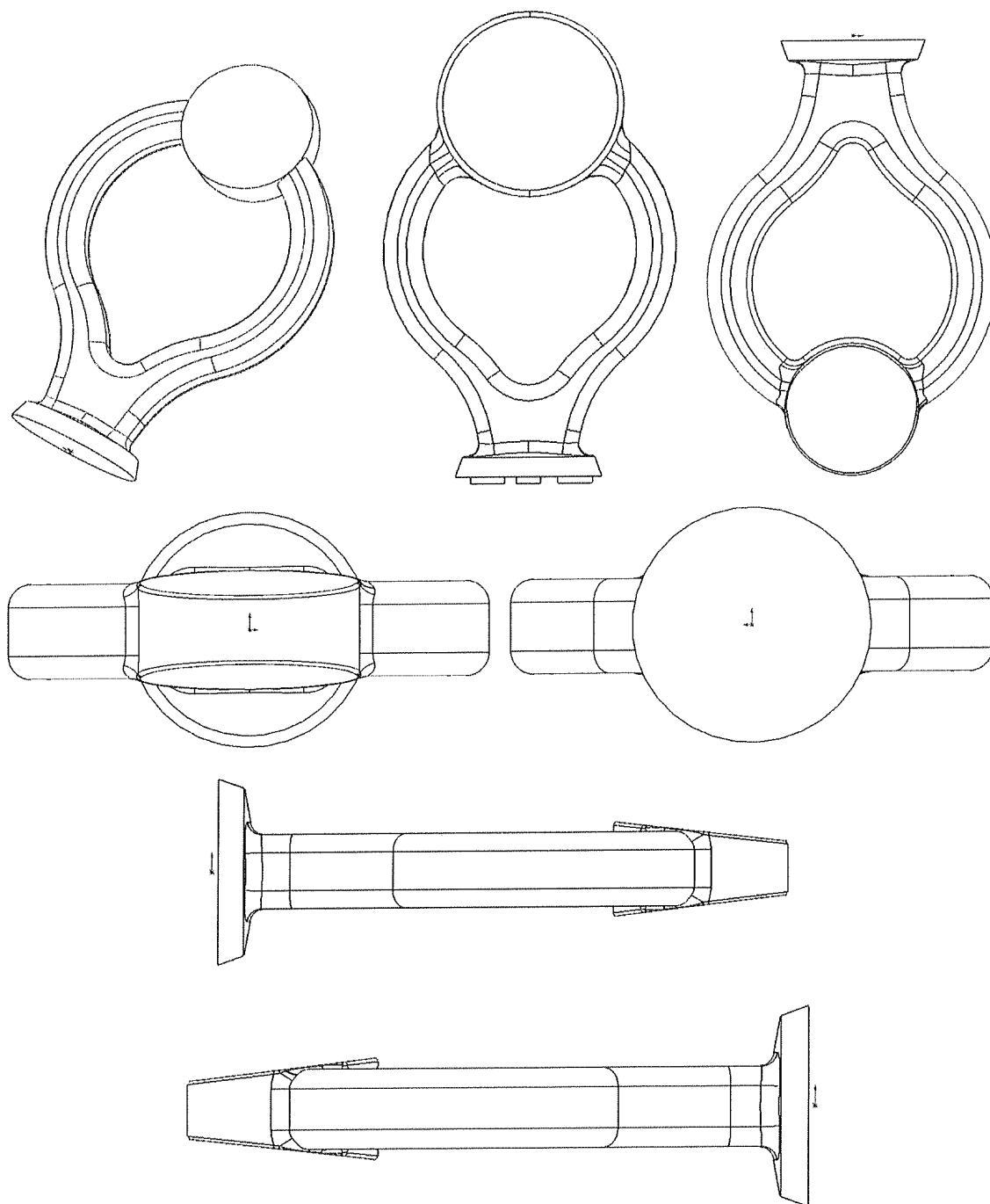


Figure 2a



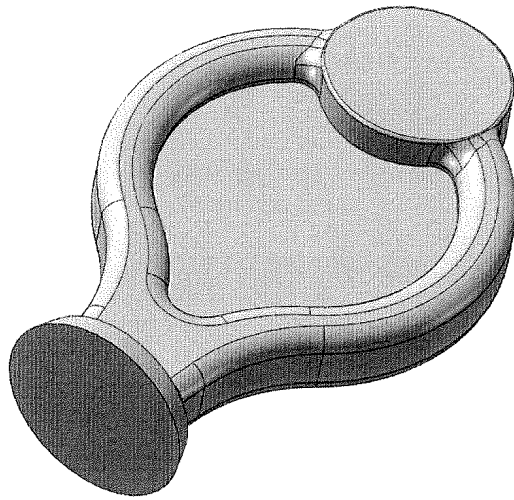
6/8

Figure 2b



7/8

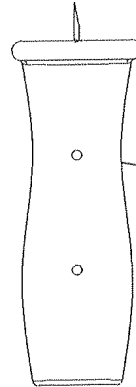
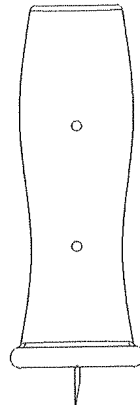
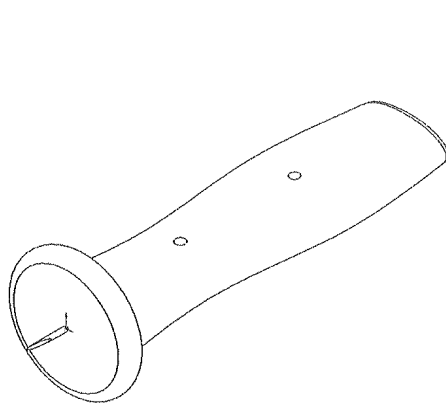
Figure 2c



9/8

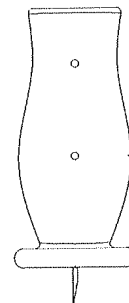
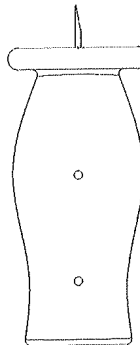
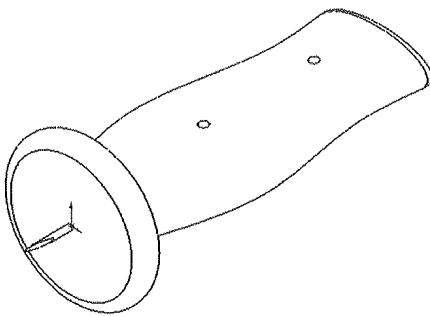
Figures 3a-3c (Varying sizes and curvatures)

Fig. 3a



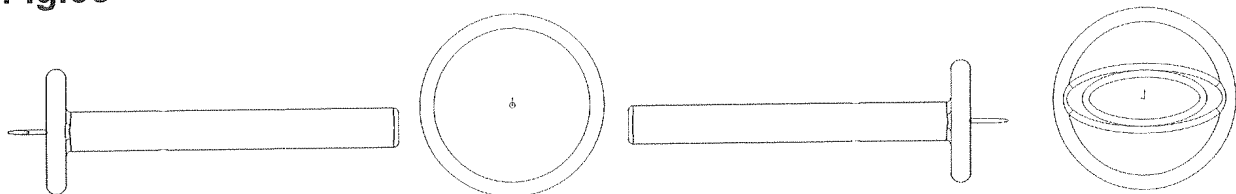
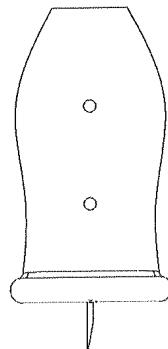
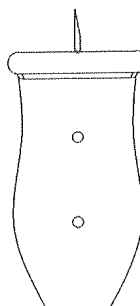
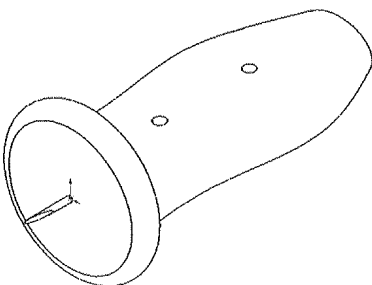
Trough: location for snap feature. Positive snap in lancet holder snaps into negative feature on lancet body. Could use trough itself for snap or could add a more defined rib or

Fig.3b



Crest: part of lancet body press fit or friction fit into lancet holder, similar to regular version (RV) lancets fitting into current devices.

Fig.3c



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

Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1

Remove

Given Name	Middle Name	Family Name	City	State	Country i
Lauren	R.	PUSEY	Kennesaw	GA	US

Inventor 2

Remove

Given Name	Middle Name	Family Name	City	State	Country i
Brian	M.	COLLINS	Marietta	GA	US

Inventor 3

Remove

Given Name	Middle Name	Family Name	City	State	Country i
Christopher	J.	RUF	Marietta	GA	US

Inventor 4

Remove

Given Name	Middle Name	Family Name	City	State	Country i
Nicholas	H.	REAVES	Atlanta	GA	US

Inventor 5

Remove

Given Name	Middle Name	Family Name	City	State	Country i
Jonathan	W.	SANDERS	Kalamazoo	MI	US

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button.**Add**

Title of Invention	LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS
Attorney Docket Number (if applicable)	2G02.1-450

Correspondence Address

Direct all correspondence to (select one):

☒ The address corresponding to Customer Number
 ☐ Firm or Individual Name

Customer Number	23506
-----------------	-------

Doc Code: **TR.PROV**

Document Description: Provisional Cover Sheet (SB16)

PTO/SB/16 (04-07)

Approved for use through 06/30/2010 OMB 0651-0032

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

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

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

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

Entity Status

Applicant claims small entity status under 37 CFR 1.27

- ☒ Yes, applicant qualifies for small entity status under 37 CFR 1.27
☐ No

Warning

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Bradley K. Groff/			Date (YYYY-MM-DD)	Jul 29, 2008
First Name	Bradley K.	Last Name	Groff	Registration Number (If appropriate)	39695

This collection of information is required by 37 CFR 1.51. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

Privacy Act Statement

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	3693988
Application Number:	61084456
International Application Number:	
Confirmation Number:	2510
Title of Invention:	LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS
First Named Inventor/Applicant Name:	Lauren R. PUSEY
Customer Number:	23506
Filer:	Bradley Groff
Filer Authorized By:	
Attorney Docket Number:	2G02.1-450
Receipt Date:	29-JUL-2008
Filing Date:	
Time Stamp:	16:04:20
Application Type:	Provisional

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1		01_ProvPatentApp.pdf	542552 5668182454b5193a5e667e7f8ac844299d7cef1f	yes	10

	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	7	
	Claims		8	9	
	Abstract		10	10	
Warnings:					
Information:					
2	Drawings-only black and white line drawings	02_InformalDrawings.pdf	366262 9d3de479114b66ee80d2260d2406b316f3c1fad7	no	8
Warnings:					
Information:					
3	Provisional Cover Sheet (SB16)	03_ProvAppCoverSheet.pdf	340518 b3d1b4a0a999f9ea0877370bcb5869f9d49c1e31a	no	4
Warnings:					
This is not a USPTO supplied Provisional Cover Sheet SB16 form.					
Information:					
Total Files Size (in bytes):			1249332		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Electronic Patent Application Fee Transmittal

Application Number:	61084456			
Filing Date:				
Title of Invention:	LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS			
First Named Inventor/Applicant Name:	Lauren R. PUSEY			
Filer:	Bradley Groff/Roseanne Hall			
Attorney Docket Number:	2G02.1-450			
Filed as Small Entity				
Provisional Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Provisional Application filing fee	2005	1	105	105
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:				
Total in USD (\$)				105

Electronic Acknowledgement Receipt

EFS ID:	3695633
Application Number:	61084456
International Application Number:	
Confirmation Number:	2510
Title of Invention:	LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS
First Named Inventor/Applicant Name:	Lauren R. PUSEY
Customer Number:	23506
Filer:	Bradley Groff/Roseanne Hall
Filer Authorized By:	Bradley Groff
Attorney Docket Number:	2G02.1-450
Receipt Date:	29-JUL-2008
Filing Date:	
Time Stamp:	16:29:39
Application Type:	Provisional

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$105
RAM confirmation Number	1897
Deposit Account	501513
Authorized User	GROFF,BRADLEY K

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

Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)

LifeScan, Inc. Ex. 1031 - Page 27

LifeScan, Inc. v. Proct Technologies LLC

IPR2023-00712 - U.S. Patent No. 8,840,635

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Fee Worksheet (PTO-06)	fee-info.pdf	8169	no	2
			c9e944567e2c988f3b055d1db6f1e763 b8667806		

Warnings:**Information:****Total Files Size (in bytes):**

8169

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

New Applications Under 35 U.S.C. 111

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

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

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

New International Application Filed with the USPTO as a Receiving Office

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



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
61/084,456	07/29/2008		105	2G02.1-450		

CONFIRMATION NO. 2510

23506
GARDNER GROFF GREENWALD & VILLANUEVA, PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

FILING RECEIPT



Date Mailed: 08/06/2008

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**

Applicant(s)

Lauren R. Pusey, Kennesaw, GA;
Brian M. Collins, Marietta, GA;
Christopher J. Ruf, Marietta, GA;
Nicholas H. Reaves, Atlanta, GA;
Jonathan W. Sanders, Kalamazoo, MI;

Power of Attorney:

Bradley Groff--39695

If Required, Foreign Filing License Granted: 08/06/2008

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/084,456**

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

Non-Publication Request: No

Early Publication Request: No

** SMALL ENTITY **

Title

LANCETS WITH IMPROVED COUPLING FEATURES AND STERILITY CAPS

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

page 1 of 3

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 (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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 Assets Control, 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).

To: 5712738300

From: 7709840098

RECEIVED
CENTRAL FAX CENTER

2-04-22 1:28pm p. 2 of 4

FEB 04 2022

Serial No.: 61/084,456
Attorney Docket No.: 2G02.1-450

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

App. Serial. No. 61/084,456)
) Conf. No.: 2510
Filed: July 29, 2008)
) Group Art Unit: N/A
For: LANCETS WITH IMPROVED COUPLING)
FEATURES AND STERILITY CAPS)

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

February 4, 2022
via Facsimile

2022 FEB -8 PM 2:31

RECEIVED
DIVISION

**CORRECTION OF ERROR IN SMALL ENTITY STATUS
AND PAYMENT OF DEFICIENCY ACCORDING TO 37 C.F.R. §1.28(c)**

Status as a small entity was established in good faith and small entity fees were paid in good faith. However, it has been discovered that small entity status was established in error and the fees identified below were inadvertently paid as a small entity. Accordingly, pursuant to 37 C.F.R. § 1.28(c), Applicant respectfully submits herewith an itemization of the total deficiency payment required, including (1) each particular type of fee that was erroneously paid as a small entity, (2) the current fee amount for a non-small entity, (3) the small entity fee actually paid and when, (4) the deficiency owed amount for each fee erroneously paid, and (5) the total deficiency payment owed. Applicant respectfully submits that the erroneous small entity fee payments were made without deceptive intent and respectfully requests excuse of this error.

Serial No.: 61/084,456
Attorney Docket No.: 2G02.1-450

FOR [FEE CODE]	FEE PAID	DATE OF PAYMENT	CURRENT FEE FOR NON-SMALL ENTITY	DEFICIENCY OWED
Provisional application filing fee [2005]	\$105	7/29/2008	\$300	\$195
			TOTAL FEES DUE:	\$195

The Commissioner is authorized to charge payment for the above-stated deficiency, and any additional fees due, to the credit card provided in the Credit Card Payment Form submitted herewith.

Respectfully submitted,

/Daniel S. Hong/
Daniel S. Hong
Reg. No. 77,670

Customer No. 23506
GARDNER GROFF & GREENWALD, PC
Tel: (770) 984-2300
Fax: (770) 984-0098

FEB 04 2022

Fax

Date: 2/4/2022
To: 5712738300
From: 7709840098
Subject: Change in Entity Status (2G02.1-450)

Thank you & best regards,
Roseanne J. McCleskey
Intellectual Property Legal Assistant
[email-footer]

Gardner Groff & Greenwald, PC
1640 Powers Ferry Road
Building 4, Suite 200
Marietta, Georgia 30067
770.984.2300 Main
770.984.0098 Fax

<https://linkprotect.cudasvc.com/url?a=http%3a%2f%2fwww.gardnergroff.com&c=E,1,FcVyU8Ru45dqFpjZo-Dlfscq6UyloYrO5dpX8t1TSN4iumNTIrf3eiWn4XyA6C3Z1B3ldthjLdYWfgduEDIPzfm41-DIB8EUH9JPwM0xtA,,&typo=1>
<https://linkprotect.cudasvc.com/url?a=http%3a%2f%2fwww.gardnergroff.com%2f&c=E,1,ribqsKFDtabJKaVwSn00cM1Fv3kocHPwsrOzFZtsCcTSP7gYkp3ao-geR91tL3w8xS3Dbtb-VeWlxl4psvLAt4EAPDfnXFmL-ByekYCG9x6B__ksC3N0Ki42&typo=1>

Follow Gardner Groff on Facebook<<https://www.facebook.com/GardnerGroffIP/>> and/or
LinkedIn<<https://www.linkedin.com/company/gardner-groff-greenwald&villanueva-pc>>

Connect with me on LinkedIn<<https://www.linkedin.com/in/roseanne-mccleskey-7aa41984/>>

This e-mail message and any attachments may contain privileged, confidential legal communications, attorney work product, and/or trade secrets solely for the use of the intended recipient. If the reader of this message is not the intended recipient, any reading, distribution, copying or other use of this message is prohibited; you should delete this message from all locations, and advise the sender at 770-984-2300 or by electronic mail. If you have not executed an engagement letter or fee contract with our firm, we do NOT represent you as your attorney and are NOT providing you with legal advice. You are encouraged to retain counsel of your choice if you desire to do so. Most legal rights have time limits, and rights can be lost if timely action is not taken. This email does not constitute advice on the application of time limitation periods unless expressly stated above. Unless we are retained as your attorney we are not responsible for monitoring or advising you of applicable deadlines. All rights of the sender for violations of confidentiality and privileges applicable to this email and any attachments are expressly reserved. Thank you.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE	REQUEST ID
61/084,456	07/29/2008	Lauren R. Pusey	2G02.1-450	158130

Acknowledgement of Loss of Entitlement to Entity Status Discount

The entity status change request below filed through Private PAIR on 02/04/2022 has been accepted.

CERTIFICATIONS:

Change of Entity Status:

☒ Applicant changing to regular undiscounted fee status.

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

This portion must be completed by the signatory or signatories making the entity status change in accordance with 37 CFR 1.4(d)(4).

Signature:	/Daniel S. Hong/
Name:	Daniel S. Hong
Registration Number:	77670



United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :67142

Sale Accounting Date:02/09/2022

Sale Item Reference Number

61084456

Effective Date

02/04/2022

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I202229E28450134	1599	MAINTENANCE/PETITION INTERNAL FEE CODE	\$195.00	Credit Card



United States Patent and Trademark Office

Office of the Chief Financial Officer

Document Code:WFEE

User :Suad Mohammed

Sale Accounting Date:06/29/2022

Sale Item Reference Number

61084456

Effective Date

02/04/2022

Document Number	Fee Code	Fee Code Description	Amount Paid	Payment Method
I20226SF15193825	1461	1.28(C) SUBMISSIONS - APPLIC FILE FEE	\$195.00	Salea



UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
61/084,456	07/29/2008	Lauren R. Pusey	2G02.1-450	2510
23506	7590	07/07/2022	EXAMINER	
GARDNER GROFF & GREENWALD, PC 1640 Powers Ferry Road Building 4, Suite 200 Marietta, GA 30067			ART UNIT	PAPER NUMBER
			NOTIFICATION DATE	DELIVERY MODE
			07/07/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@dockettrak.com
patent@gardnergroff.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

In re Application of :
Pusey et al. :
Application No. 61/084,456 :
Filed: July 29, 2008 : NOTICE
For: LANCETS WITH IMPROVED :
COUPLING FEATURES AND :
STERILITY CAPS :

This is a Notice regarding the request for acceptance of a fee deficiency submission under 37 CFR 1.28(c) filed February 4, 2022.

There is no indication that the petition is signed by a registered patent attorney or patent agent of record. However, in accordance with 37 CFR 1.34, the signature of Daniel S. Hong appearing on the correspondence shall constitute a representation to the United States Patent and Trademark Office that he or she is authorized to represent the particular party on whose behalf he or she acts.

The Office no longer investigates or rejects original or reissue applications under 37 CFR 1.56. 1098 Off. Gaz. Pat. Office 502 (January 3, 1989). Therefore, nothing in this Notice is intended to imply that an investigation was done.

The fee deficiency submission under 37 CFR 1.28(c) is **ACCEPTED**. Accordingly, status as a small entity has been removed.

Inquiries related to this communication should be directed to Jamice Brantley at (571) 272-3814.

/Andrea Smith/

Andrea Smith
Lead Paralegal Specialist, Office of Petitions