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1192454

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

February 28, 2022

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

APPLICATION NUMBER: *17/172,506*

FILING DATE: *February 10, 2021*

RELATED PCT APPLICATION NUMBER: *PCT/US22/16019*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS *US17/172,506*



Certified by

Anders Iversen

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

Electronic Acknowledgement Receipt

EFS ID:	41889859
Application Number:	17172506
International Application Number:	
Confirmation Number:	3497
Title of Invention:	Testicular Implant Device and Method
First Named Inventor/Applicant Name:	James J. Elist
Customer Number:	103072
Filer:	Lara Alexandra Petersen
Filer Authorized By:	
Attorney Docket Number:	
Receipt Date:	10-FEB-2021
Filing Date:	
Time Stamp:	14:31:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 830
RAM confirmation Number	E202120E31510001
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Oath or Declaration filed	Dec.pdf	205137	no	2
			2e51e4e01ca012a8eb2232c4c9f47ed6a2e91446		
Warnings:					
Information:					
2	Application Data Sheet	ADS.pdf	1255737	no	8
			67ca58b9dce0bf27b48bab8de6982afc5981f9ad		
Warnings:					
Information:					
3	Specification	Spec.pdf	148812	no	19
			124e2f2fd3490da45e060e5f7ca454babe971e7e		
Warnings:					
Information:					
4	Claims	Claims.pdf	56406	no	4
			2fd82867ae9a59514d5e955ae873ea793921031c		
Warnings:					
Information:					
5	Abstract	Abstract.pdf	40948	no	1
			1e4452a89337915c696389897a0ad162858ad839		
Warnings:					
Information:					
6	Drawings-only black and white line drawings	Drawings.pdf	881380	no	4
			12bb0a2628f9c372f7f51e1335636fa5146db8		
Warnings:					
Information:					

7	Information Disclosure Statement (IDS) Form (SB08)	IDS.pdf	1034464	no	5
			5ddd385e9e5424bb6ee745a89390320880b3c65e		

Warnings:

Information:

8	Fee Worksheet (SB06)	fee-info.pdf	34878	no	2
			451def53d4a35cf785751a3474cb74d6127f99c1		

Warnings:

Information:

Total Files Size (in bytes):			3657762
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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.

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

**Title of
Invention**

TESTICULAR IMPLANT DEVICE AND METHOD

As the below named inventor, I hereby declare that:

This declaration
is directed to:

☒

The attached application, or

☐

United States application or PCT international application number _____
filed on _____.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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 the 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.

LEGAL NAME OF INVENTOR

Inventor: James J. Elist, MD

Date (Optional) : _____

Signature: _____



Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

Privacy Act Statement

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

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

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

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)
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Inventor Information:

Inventor	1				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
Dr. ▾	James	J.	Elist	▾		
Residence Information (Select One) • ☒ US Residency ☐ Non US Residency ☐ Active US Military Service						
City	Beverly Hills	State/Province	CA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	8500 Wilshire Blvd, Suite 707					
Address 2						
City	Beverly Hills	State/Province	CA			
Postal Code	90211	Country i	US			
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	103072		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	Testicular Implant Device and Method		
Attorney Docket Number		Small Entity Status Claimed ☒	
Application Type	Nonprovisional ▾		
Subject Matter	Utility ▾		
Total Number of Drawing Sheets (if any)	4	Suggested Figure for Publication (if any)	1

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	103072		

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

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ⁱ (if applicable)	Remove

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button.

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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.

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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
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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	Menova International, Inc.		
-------------------	----------------------------	--	--

Mailing Address Information For Applicant:

Address 1	3500 Wilshire Blvd, Suite 707		
Address 2			
City	Beverly Hills	State/Province	CA
Country	US	Postal Code	90211
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.

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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.			☒
Organization Name	Menova International, Inc.		
Mailing Address Information For Assignee including Non-Applicant Assignee:			
Address 1	3500 Wilshire Blvd, Suite 707		
Address 2			
City	Beverly Hills	State/Province	CA
Country i	US	Postal Code	90211
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	/OEK/		Date (YYYY-MM-DD)	2021-02-10
First Name	Omid	Last Name	Khalifeh	Registration Number
Additional Signature may be generated within this form by selecting the Add button.				Add

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	
		Application Number	
Title of Invention	Testicular Implant Device and Method		

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

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

IN
THE UNITED STATES PATENT
AND TRADEMARK OFFICE
UTILITY PATENT APPLICATION
OF
JAMES J. ELIST, M.D.
FOR
TESTICULAR IMPLANT
DEVICE AND METHOD

GOVERNMENT CONTRACT

[0001] Not applicable.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0002] Not applicable.

STATEMENT RE. FEDERALLY SPONSORED RESEARCH/DEVELOPMENT

[0003] Not applicable.

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TECHNICAL FIELD

[0005] The disclosed subject matter relates generally to surgically implanted devices and methods and, more particularly, to surgically implanted prostheses for the enhancement and enlargement of the appearance of the testicles and scrotum.

BACKGROUND

[0006] The anatomy of the male reproductive system generally comprises the penis and testicles. The penis acts as a conduit for urine to leave the body and also functions as the male sex organ. On the other hand, the testicles, also known as testes (and individually, a “testis”), are the

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glands where sperm and testosterone are produced. The scrotum, or scrotal sac, is a muscular sac that contains and protects the testicles, blood vessels and part of the spermatic cord. Moreover, the tunica vaginalis is a pouch of serous membrane covering the testes. The scrotum is located behind and underneath the penis.

[0007] Some individuals experience a small or unnatural looking scrotal area. For instance, individuals who use exogenous testosterone often experience a noticeable decrease in testicular size. Other conditions, including removal of one or both testicles due to cancer, testicular atrophy, undescended testicles, and originally smaller size of the testicles compared to the scrotal sac, may result in abnormally shaped or smaller than average scrotum size. In any event, a surgical correction of the aesthetic appearance of the scrotum may be required or desired. To that end, some testicular implants have attempted to correct this issue with limited success.

[0008] For instance, U.S. Patent No. 5,662,709 teaches an implant device for improving the size and shape of a testis and configured to be implanted within a scrotum and attach to the testis. While this implant is well suited for male patients suffering from small gonad size or malformity, this device does not comprise one or more layers of net sheeting so as to add structure thereto. Thus, this teaching is deficient because it does not provide an implant of sufficient rigidity and which may be easily sutured to the patient’s gonads.

[0009] Another attempt is seen with regard to U.S. Patent No. 4,726,360, which teaches a penile prosthesis adapted for the treatment of erectile impotence. This disclosure provides an elongated flexible member for implantation within the corpus cavernosum of the penis and a pressure bulb configured to transfer fluid to the member. This teaching is also deficient because it fails to provide the natural appearance and feeling of the testicles, as provided by the present invention.

[0010] None of the aforementioned attempts comprise the advantages of the present invention. As such, there remains a need for a testicular implant for improving the size, symmetry, and appearance of the testes and/or scrotum.

SUMMARY

[0011] The present disclosure is directed to testicular implant devices that may expand the size of the scrotum and enhance overall scrotal appearance. More particularly, the testicular implant device may improve the appearance of the scrotal sac by providing symmetry to disproportionate testicles and increasing testicle size. Further, the testicular implant may appear natural in appearance and feeling to the unknowing observer.

[0012] For purposes of summarizing, certain aspects, advantages, and novel features have been described. It is to be understood that not all such advantages may be achieved in accordance with any one particular embodiment. Thus, the disclosed subject matter may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages without achieving all advantages as may be taught or suggested.

[0013] In accordance with one embodiment, the testicular implant may comprise a generally spherical, hollow body and a cavity. The generally spherical, hollow body may be configured to be implanted within a scrotum and thus, may be sized to be inserted into the scrotal sac via scrotal surgery. The cavity may be sized to receive a testis and may further comprise a cavity edge.

[0014] In some embodiments, the implant may be implantable within the scrotum having small testicles, that is, testicles which may be smaller than desired by the patient or those which are smaller than average. In such embodiments, the implant may serve to augment the testis without having any testicular function, such as hormone production. In alternate embodiments, the

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implant may be implantable within the scrotum having the testis which may be disproportionate in shape and/or size. In these embodiments, the implant may serve to symmetrize the existing testis. In still further embodiments, the implant may be implantable within the scrotum, wherein the scrotum may be pendulous or may comprise a large scrotal web. In such embodiments, the implant may serve to fill out the scrotum.

[0015] The spherical, hollow body may be formed so as to generally mimic the shape of a natural testis. In this manner, the body may expand the size of the scrotum. According to certain embodiments, the body may range between approximately 0.5 inches to 6 inches in diameter. In alternative embodiments, the body may be 6 inches or greater in diameter. A person of ordinary skill in the art will recognize the body may be formed in other shapes and sizes as well.

[0016] Moreover, the body may comprise one or more layers of net sheeting. The net sheeting may be stretchable and provide added structure to the implant. The net sheeting may be formed out of polypropylene, silicone, bovine tissue, marbles, strings, or other biocompatible material. In certain embodiments, the net sheeting may be laid out in a rectangular gird. The net sheeting may also facilitate suturing of the implant to the scrotum and/or the existing testis, as the case may be. In this manner, in some embodiments, the net sheeting may be disposed along the cavity edge, thereby spanning the inner circumference of the cavity.

[0017] The cavity may be concave and generally curve-shaped. In some embodiments, the cavity may comprise precisely enough space for the testis. In other embodiments, the cavity may be sized to receive the testis and also, provide additional space surrounding the testis. In still further embodiments where the testis has been removed or is otherwise smaller than normal, the cavity may comprise much less space.

[0018] As mentioned previously, the cavity may have the cavity edge. The cavity edge may serve as a means of ingress into the cavity. In this way, in embodiments where the testis may still be attached, the testis may fit through the cavity edge and into the cavity. Alternatively, the cavity edge (and therefore, the cavity) may encompass the spermatic cord or other portion of the scrotal sac.

[0019] In certain embodiments, the testicular implant may be formed out of a biocompatible material. As examples, the biocompatible material may comprise medical-grade silicone and/or medical-grade polyester. Alternatively, the testicular implant may be formed out of a gel-like material or may comprise saline, marbles, or other materials. In addition, the testicular implant may comprise one or more air pockets. Further, the testicular implant may be formed of one or more internal layers, which may provide rigidity. The testicular implant may feel soft and smooth along its surface area. In other embodiments, the testicular implant may feel textured along its surface area. Indeed, it is an objective of the present invention to provide a natural feeling and looking testicular implant.

[0020] In some embodiments, the testicular implant may comprise one or more functional layers. Any one of the one or more functional layers may be secured to the body, the cavity, and/or the cavity edge. While a number of functions performed or supported by the one or more functional layers are contemplated, the one or more functional layers may comprise antimicrobial, antibacterial, and/or antibiotic layers. In other embodiments, the one or more functional layers may be anti-adhesive, slick or lubricious layers, anti-inflammatory layers, controlled release layers, fluid reduction layers, or even a multifunctional combination of one or more of the foregoing.

[0021] Further, the implant may comprise an antibacterial, antimicrobial and/or antibiotic coating along either or both of an inner surface and an outer surface of the body. The antimicrobial,

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antibiotic and/or antibacterial coating may prevent infection from bacteria in or around the surgical site during or after implantation. Any antibacterial, antibiotic or antimicrobial coating known to those skilled in the art may be applied to the implant.

[0022] In one embodiment of the present invention, a method involving the aforementioned testicular implant device may be used to enhance to cosmetic appearance of the scrotum and the testes. The method may comprise the steps of: administering one or more anesthetic agents to a patient having at least one testis and a scrotum; cutting an at least 1.5-inch longitudinal incision in the scrotum to expose the tunica vaginalis; cutting an at least 1.5-inch longitudinal incision in the tunica vaginalis; providing a testicular implant having a generally spherical, hollow body and one or more layers of net sheeting; placing the testicular implant over the at least one testis; closing the at least 1.5-inch longitudinal incision in the tunica vaginalis; connecting the testicular implant to the tunica vaginalis; and closing the scrotum.

[0023] One or more of the above-disclosed embodiments, in addition to certain alternatives, are provided in further detail below with reference to the attached figures. The disclosed subject matter is not, however, limited to any particular embodiment disclosed.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a perspective view of an embodiment of the testicular implant device.

FIG. 2 shows a side view of an embodiment of the testicular implant device.

FIG. 3 shows a perspective view of an embodiment of the testicular implant device.

FIG. 4 shows a cross-section view of an embodiment of the testicular implant device.

FIG. 5 shows an embodiment of the testicular implant method.

[0024] The disclosed embodiments may be better understood by referring to the figures in the attached drawings, as provided below. The attached figures are provided as non-limiting

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examples for providing an enabling description of the method and system claimed. Attention is called to the fact, however, that the appended drawings illustrate only typical embodiments of this invention and are therefore not to be considered as limiting of its scope. One skilled in the art will understand that the invention may be practiced without some of the details included in order to provide a thorough enabling description of such embodiments. Well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments.

[0025] For simplicity and clarity of illustration, the drawing figures illustrate the general manner of construction, and descriptions and details of well-known features and techniques may be omitted to avoid unnecessarily obscuring the invention. Additionally, elements in the drawing figures are not necessarily drawn to scale. For example, the dimensions of some of the elements in the figures may be exaggerated relative to other elements to help improve understanding of embodiments of the present invention. The same reference numerals in different figures denote the same elements.

[0026] The terms “first,” “second,” “third,” “fourth,” and the like in the description and in the claims, if any, are used for distinguishing between similar elements and not necessarily for describing a particular sequential or chronological order. It is to be understood that the terms so used are interchangeable under appropriate circumstances such that the embodiments described herein are, for example, capable of operation in sequences other than those illustrated or otherwise described herein. Furthermore, the terms “include,” and “have,” and any variations thereof, are intended to cover a non-exclusive inclusion, such that a process, method, system, article, device, or apparatus that comprises a list of elements is not necessarily limited to those elements, but may

include other elements not expressly listed or inherent to such process, method, system, article, device, or apparatus

[0027] The terms “couple,” “coupled,” “couples,” “coupling,” and the like should be broadly understood and refer to connecting two or more elements or signals, electrically, mechanically or otherwise. Two or more electrical elements may be electrically coupled, but not mechanically or otherwise coupled; two or more mechanical elements may be mechanically coupled, but not electrically or otherwise coupled; two or more electrical elements may be mechanically coupled, but not electrically or otherwise coupled. Coupling (whether mechanical, electrical, or otherwise) may be for any length of time, e.g., permanent or semi-permanent or only for an instant.

DETAILED DESCRIPTION

[0028] Having summarized various aspects of the present disclosure, reference will now be made in detail to that which is illustrated in the drawings. While the disclosure will be described in connection with these drawings, there is no intent to limit it to the embodiment or embodiments disclosed herein. Rather, the intent is to cover all alternatives, modifications and equivalents included within the spirit and scope of the disclosure as defined by the appended claims.

[0029] With reference to **FIGS. 1-4**, a testicular implant **10** is provided that, in some embodiments, may increase scrotal size while maintaining the natural look and feel thereof. In addition to increasing the apparent size of a patient’s scrotum **30** and enhancing overall scrotal appearance, the implant **10** may also symmetrize the testes (individually, a testis **40**). Further, the implant **10** may fill out the scrotal sac **30** for patients experiencing a pendulous scrotum or a large scrotal web. As another example, the implant **10** may be implanted where the patient naturally has

undescended or small testicles. Further, the testicular implant **10** may improve a patient’s self-confidence, self-esteem, and overall self-satisfaction.

[0030] As shown in **FIG. 1**, the testicular implant **10** may comprise a generally spherical, hollow body **20** and a cavity **25**. The body **20** may be configured to be implanted within the scrotum **30**. Accordingly, the body **20** may be sized so as to fit within the scrotal sac **30** as implanted during scrotal surgery. The body **20** may be attached to the scrotal sac **30** or the testis **40** using a biocompatible connecting agent. For instance, the biocompatible connecting agent may comprise sutures, adhesive, staples, or any other biocompatible material. As a whole, the implant **10** may not provide testicular function to the patient but instead, serves an aesthetic utility. In such embodiments, the body **20** may be slightly larger so as to sufficiently fill the scrotal sac **30** and provide a fuller, rounded appearance thereto.

[0031] The spherical, hollow body **20** may be cup-shaped and ovular. As such, the body **20** may be configured to be placed around the testis **40** or spermatic cord **35**. Of course, as previously mentioned, the body **20** may also be secured to the scrotum **30**. In certain embodiments, the body **20** may be configured so as to mimic the shape of the testis **40**. By way of illustration, the body **20** may range between approximately 0.5 inches and 6 inches in diameter. Alternatively, the body **20** may be 6 inches or greater in diameter. Overall, the body **20** may be bigger or smaller depending on the patient’s size and preferences. Moreover, in some embodiments, the body **20** may be custom molded for the patient in accordance with selected physical dimensions.

[0032] As shown with greater detail in **FIGS. 2-3**, body **20** may also comprise one or more layers of net sheeting **22**. It should be noted that, in some embodiments, the net sheeting **22** may not be visible from an outer surface of the body **20**. In such embodiments, the one or more layers of net sheeting **22** may be imbedded within an inner surface (obscured from view) of the body **20**.

As shown and described herein, the one or more layers of net sheeting **22** may be imbedded within the outer surface of the body **20** and therefore, the net sheeting **22** may be visible from the outer surface of the body **20**.

[0033] The one or more layers of net sheeting **22** may provide rigidity to the testicular implant **10** while also being stretchable. In accordance with certain embodiments, the one or more layers of net sheeting **22** may be formed out of polypropylene, silicone, bovine tissue, marbles, or strings. One of ordinary skill in the art will appreciate that the net sheeting **22** may be formed out of other medically-safe, biocompatible materials as well. In other embodiments, the net sheeting **22** may be formed out of non-biocompatible materials.

[0034] The net sheeting **22** may be formed of cross-hatched filaments, that is, filaments laid out in a rectangular grid. In other embodiments, the net sheeting **22** may be formed out of other geometric patterns or even, non-geometric patterns. In embodiments where the implant **10** may comprise more than one layer of net sheeting **22**, each layer may be placed along the body **20** in opposing spaced-apart configurations so as to not steering the implant **10** in either lateral direction. In certain embodiments, the net sheeting **22** may comprise filaments having approximately 1/32 inch thickness and 1/32 inch spacing. In this manner, the net sheeting **22** may also facilitate suturing of the implant **10** to the testis **40**, the spermatic cord **35**, or elsewhere along the scrotum **30**.

[0035] With reference to **FIG. 3**, the one or more layers of net sheeting **22** may comprise a mesh ring **24**. The mesh ring **24** may be disposed along the cavity edge **27**. Stated differently, the mesh ring **24** may extend along the inner circumference of the cavity **25**. In such embodiments, the mesh ring **24** may align and surround the testis **40** and may facilitate suturing of the implant **10** to the testis **40**.

[0036] With attention to any of **FIGS. 1-4**, the cavity **25** may comprise a cavity edge **27**. The cavity edge **27** may define an opening of the cavity **25** and therefore, a means of ingress into the cavity **25**. The body **20** may be secured to the testis **40**, scrotum **30**, spermatic cord **35** or elsewhere via the cavity edge **27**. Specifically, the body **20** may be attached, such as by using the biocompatible connecting agent, to the patient along the cavity edge **25**. In some embodiments, the entirety of the cavity edge **27** may be attached to the patient. In other embodiments, only a part of the cavity edge **27** may be attached to the patient.

[0037] Because the body **20** may be cup-shaped, the cavity **25** be correspondingly be curved and concave. In some embodiments, the cavity **25** may be sized to receive the testis **40**. According to certain of those embodiments, the cavity **25** may be sized to receive the testis **40** and provide additional space surrounding the testis **40**. Alternatively, the cavity **25** may be sized so as to fill out the scrotal sac **30** and therefore, may provide precisely enough space for the testis **40**.

[0038] The testicular implant **10** may be formed out of a soft, smooth, and flexible material. Alternatively, the implant **10** may be formed out of a textured material. In accordance with certain embodiments, the out of a biocompatible material. As an example, the implant **10** may be formed out of medical-grade silicone, medical-grade polyester, medical-grade polypropylene, or a combination of the foregoing. One of ordinary skill in the art will appreciate that the testicular implant **10** may be formed out of other medically-safe, biocompatible materials as well.

[0039] According to further embodiments, the testicular implant **10** may comprise a gel-like material, saline, marbles, or other materials. In certain embodiments, the testicular implant **10** may be formed of one or more internal layers. Further, the one or more internal layers may comprise one or more air pockets. In other embodiments, the implant **10** may comprise a

stretchable material. Overall, it is an object of the present invention to provide an implant **10** which is natural in look and feel.

[0040] In certain embodiments, the implant **10** may be formed of one or more functional layers. A number of exemplary, but not limited, functions performed or supported by the one or more functional layers are contemplated. For instance, in some embodiments, the one or more functional layers may be antimicrobial, antibacterial, and/or antibiotic layers. Such layers may comprise an antibiotic solution, or even one or more chemical elements or agents known to those skilled in the art as operative to kill microorganisms and/or stop their growth such as silver, copper, zinc, and ferric ammonium coatings, among others. In some embodiments, the one or more functional layers may be anti-adhesive. In such cases the one or more functional layers may comprise a hydrophilic coating which will be known to those skilled in the art. In some embodiments, the one or more functional layers may be slick or lubricious layers comprising a silicone coating. In some embodiments, the one or more functional layers may be anti-inflammatory layers comprising steroid coatings. In some embodiments, the one or more functional layers may be controlled release layers. In some embodiments, the one or more functional layers may be fluid reduction layers such as hydrogenated amorphous carbon coatings known to those skilled in the art.

[0041] It is even contemplated that in some embodiments, the one or more functional layers may comprise multifunctional coatings operative to perform a combination of the aforementioned exemplary functions, among others known to those skilled in the art. Likewise, one or more functions performed or supported by the one or more functional layers may be combined or otherwise stacked without departing from the invention. In some of these embodiments, the one or more functional layers may be embedded or impregnated within the

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implant **10**. In other embodiments, the one or more functional layers may be secured to the body **20**, the cavity **25**, or the cavity edge **27** while the implant **10** is implanted within the patient’s scrotum.

[0042] Further, the testicular implant **10** or one or more of the one or more layers of net sheeting **22** may be coated with one or more of an antibacterial coating, an antimicrobial coating, or an antibiotic coating (collectively referred to as the “coating”). The coating may reduce the risk of infection of the surgical site by immobilizing bacteria and providing continuous antimicrobial activity, thereby disallowing bacteria on the skin to infect the surgical site. Such coating may comprise iodine, active chlorine, concentrated alcohols, phenolic substances, cationic substances, oxidizers, heavy metals, strong acids, and alkalis.

[0043] With reference to **FIG. 5**, one embodiment of the present invention may involve a method of implanting the aforementioned testicular implant device. **FIG. 5** illustrates a flowchart of one embodiment of the method of this invention. This method may improve scrotal appearance by cosmetically correcting conditions such as small testicles, disproportionate scrotum, and other related diagnoses. In particular, the method may provide additional size to the testicles, thereby enhancing the size of the scrotum. Additionally, the method may symmetrize the testicles.

[0044] In certain embodiments, including that demonstrated in **FIG. 5**, the method may comprise the steps of: administering one or more anesthetic agents to a patient having at least one testis and a scrotum (block **501**); cutting an at least 1.5-inch longitudinal incision in the scrotum to expose the tunica vaginalis (block **502**); cutting an at least 1.5-inch longitudinal incision in the tunica vaginalis (block **503**); providing a testicular implant having a generally spherical, hollow body and one or more layers of net sheeting (block **504**); placing the testicular implant over the at least one testis (block **505**); closing the at least 1.5-inch longitudinal incision in the tunica vaginalis

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(block **506**); connecting the testicular implant to the tunica vaginalis (block **507**); and closing the scrotum (block **508**).

[0045] Initially, the one or more anesthetic agents may be administered (block **501**). The one or more anesthetic agents may render the patient unconscious or otherwise alter or reduce the patient’s conscious state, sensation and perception of pain resulting from the procedure. In some embodiments, the one or more anesthetic agents may comprise general anesthesia or spinal anesthesia. In further embodiments, the one or more anesthetic agents may comprise general twilight anesthesia. In these embodiments, the general anesthesia may be administered in a mild dose so as to cause mild sedation and anxiolysis. In other embodiments, the one or more anesthetic agents may comprise a local anesthetic agent. For instance, the one or more anesthetic agents may be injected around the scrotal area. In such embodiments, the one or more anesthetic agents may comprise the local anesthetic agent, such as lidocaine, other long-acting local anesthetic agents, or combinations thereof.

[0046] Once the one or more anesthetic agents have been administered (block **501**), the at least 1.5-inch longitudinal incision may be cut in the scrotum (block **502**). In so doing, the tunica vaginalis may be exposed. After the 1.5-inch incision has been cut (block **502**), the testicular implant may be provided (block **504**). In some embodiments, the testicular implant may be similar or identical to that described above with regard to the testicular implant device. Moreover, in certain embodiments, providing the testicular implant (block **504**) may further comprise selecting an appropriately-sized testicular implant. For instance, the appropriately-sized testicular implant may be based on the patient’s anatomy or desired outcome.

[0047] Next, the testicular implant may be placed over the at least one testis (block **505**). The testicular implant may be placed over the at least one testis along the cavity edge of the

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implant, as described above. Stated differently, the cavity of the testicular implant may receive the at least one testis, thereby causing the cavity edge to abut the testis. In some embodiments, only a part of the cavity edge may abut and ultimately secure to the at least one testis. In other embodiments, the entirety of the cavity edge may abut and secure to the testis.

[0048] After the testicular implant has been placed over the at least one testis (block **505**), the at least 1.5-inch longitudinal incision in the tunica vaginalis may be closed (block **506**). According to certain embodiments, the 1.5-inch longitudinal incision may be closed using any biocompatible connecting agent. By way of example, the biocompatible connecting agent may comprise sutures, staples, or adhesive.

[0049] Similarly, the testicular implant may then be connected to the tunica vaginalis using a biocompatible connecting agent (block **507**). In accordance with certain embodiments, the one or more layers of net sheeting may be sutured to the tunica vaginalis. Finally, the scrotum may be closed (block **508**). In certain embodiments, the scrotum may likewise be closed using a biocompatible connecting agent. In some embodiments, the same biocompatible connecting agent may be used to close the 1.5-inch longitudinal incision in the tunica vaginalis (block **506**), connect the testicular implant to the tunica vaginalis (block **507**), and close the scrotum (block **508**). In alternate embodiments, a different biocompatible connecting agent may be used.

[0050] In further embodiments, the testicular implant method may also comprise trimming the testicular implant to a desired form. The desired form may be based on the size of the at least one testis. In this manner, the desired form may accommodate the natural shape and size of the at least one testis. In some embodiments, the desired form may also be based on the desires of the patient.

[0051] In still further embodiments, the testicular implant method may further comprise irrigating with one or more antibiotic agents. In some embodiments, the one or more antibiotic agents may comprise a triple antibiotic solution with rifampicin. In alternate embodiments, the one or more antibiotics may comprise a triple antibiotic solution mixed with minocycline or a combination of rifampicin and minocycline. However, other antibiotics or antibiotic solutions may be applied in accordance with the method. Indeed, a person of ordinary skill in the art will recognize other such appropriate antibiotics. The one or more antibiotics may inhibit or slow the growth of bacteria in the surgical site.

[0052] It should be emphasized that the above-described embodiments are merely examples of possible implementations. Many variations and modifications may be made to the above-described embodiments without departing from the principles of the present disclosure. All such modifications and variations are intended to be included herein within the scope of this disclosure and protected by the following claims.

[0053] Moreover, embodiments and limitations disclosed herein are not dedicated to the public under the doctrine of dedication if the embodiments and/or limitations: (1) are not expressly claimed in the claims; and (2) are or are potentially equivalents of express elements and/or limitations in the claims under the doctrine of equivalents.

CONCLUSIONS, RAMIFICATIONS, AND SCOPE

[0054] While certain embodiments of the invention have been illustrated and described, various modifications are contemplated and can be made without departing from the spirit and scope of the invention. For example, the testicular implant device and method may be implanted if the patient has smaller than desired testicles or testicles that are disproportionate. Accordingly, it is intended that the invention not be limited, except as by the appended claims.

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[0055] The teachings disclosed herein may be applied to other systems, and may not necessarily be limited to any described herein. The elements and acts of the various embodiments described above can be combined to provide further embodiments. All of the above patents and applications and other references, including any that may be listed in accompanying filing papers, are incorporated herein by reference. Aspects of the invention can be modified, if necessary, to employ the systems, functions and concepts of the various references described above to provide yet further embodiments of the invention.

[0056] Particular terminology used when describing certain features or aspects of the invention should not be taken to imply that the terminology is being refined herein to be restricted to any specific characteristics, features, or aspects of the testicular implant device and method with which that terminology is associated. In general, the terms used in the following claims should not be constructed to limit the testicular implant device and method to the specific embodiments disclosed in the specification unless the above description section explicitly define such terms. Accordingly, the actual scope encompasses not only the disclosed embodiments, but also all equivalent ways of practicing or implementing the disclosed system, method and apparatus. The above description of embodiments of the testicular implant device and method is not intended to be exhaustive or limited to the precise form disclosed above or to a particular field of usage.

[0057] While specific embodiments of, and examples for, the method, system, and apparatus are described above for illustrative purposes, various equivalent modifications are possible for which those skilled in the relevant art will recognize.

[0058] While certain aspects of the method and system disclosed are presented below in particular claim forms, various aspects of the method, system, and apparatus are contemplated in any number of claim forms. Thus, the inventor reserves the right to add additional claims after

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filing the application to pursue such additional claim forms for other aspects of the testicular implant device and method.

CLAIMS

What is claimed is:

1. A testicular implant, comprising:

a generally spherical, hollow body configured to be implanted within a scrotum and having one or more layers of net sheeting; and

a cavity sized to receive a testis and having a cavity edge.
2. The testicular implant of claim 1, wherein the implant is formed of a biocompatible material.
3. The testicular implant of claim 1, wherein the implant is formed of a gel-like material, saline, marbles, or one or more internal layers formed of one or more of medical-grade silicone, polyester, and one or more air pockets.
4. The testicular implant of claim 1, wherein the one or more layers of net sheeting are formed of polypropylene, silicone, bovine tissue, or other biocompatible material.
5. The testicular implant of claim 1, wherein the body attaches within the scrotum using a biocompatible connecting agent.
6. The testicular implant of claim 1, wherein the one or more layers of net sheeting attach the body to the tunica vaginalis.

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7. The testicular implant of claim 6, wherein the one or more layers of net sheeting attach the body to the tunica vaginalis using a biocompatible connecting agent.
8. The testicular implant of claim 7, wherein the biocompatible connecting agent is sutures.
9. The testicular implant of claim 1, further comprising one or more functional layers.
10. The testicular implant of claim 9, wherein the one or more functional layers comprises one or more of antibiotic layers, antimicrobial layers, antibacterial layers, anti-adhesive layers, hydrophilic coating, lubricious layers, anti-inflammatory layers, controlled release layers, and fluid reduction layers.
11. The testicular implant of claim 1, wherein the body is at least 0.5 inches in diameter.
12. A testicular implant, comprising:
a generally spherical, hollow body configured to be implanted within a scrotum and having one or more layers of net sheeting; and
a cavity sized to receive a testis and having a cavity edge, wherein the body attaches within the scrotum along the cavity edge using sutures.
13. A testicular implant method, comprising the steps of
administering one or more anesthetic agents to a patient having at least one testis and a scrotum;

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cutting an at least 1.5-inch longitudinal incision in the scrotum to expose tunica vaginalis;
cutting an at least 1.5-inch longitudinal incision in the tunica vaginalis;
providing a testicular implant having a generally spherical, hollow body and one or more layers of net sheeting;
placing the testicular implant over the at least one testis;
closing the at least 1.5-inch longitudinal incision in the tunica vaginalis;
connecting the testicular implant to the tunica vaginalis; and
closing the scrotum.

14. The testicular implant method of claim 13, wherein the testicular implant further comprises a cavity sized to receive a testis.

15. The testicular implant of claim 14, wherein placing the testicular implant over the at least one testis further comprises placing the cavity over the at least one testis.

16. The testicular implant method of claim 13, wherein connecting the testicular implant to the tunica vaginalis further comprises suturing the testicular implant to the tunica vaginalis.

17. The testicular implant method of claim 16, wherein suturing the testicular implant to the tunica vaginalis further comprises suturing the one or more layers of net sheeting to the tunica vaginalis.

18. The testicular implant method of claim 13, further comprising

Patent Application of James J. Elist, M.D.
For "Testicular Implant Device and Method"

trimming the testicular implant to a desired form, wherein the desired form is based on the size of the at least one testis.

19. The testicular method of claim 13, further comprising
irrigating with one or more antibiotic agents.

ABSTRACT

A testicular implant device and method is provided. The testicular implant device comprises a generally spherical, hollow body configured to be implanted within a scrotum and a cavity sized to receive a testis. The spherical, hollow body has one or more layers of net sheeting, which provides structural rigidity to the implant and facilitates suturing of the implant to the patient. The cavity also has a cavity edge, which defines a means of ingress into the cavity. The method comprises the steps of administering one or more anesthetic agents to a patient having at least one testis and a scrotum; cutting an at least 1.5-inch longitudinal incision in the scrotum to expose the tunica vaginalis; cutting an at least 1.5-inch longitudinal incision in the tunica vaginalis; providing a testicular implant having a generally spherical, hollow body and one or more layers of net sheeting; placing the testicular implant over the at least one testis; closing the at least 1.5-inch longitudinal incision in the tunica vaginalis; connecting the testicular implant to the tunica vaginalis; and closing the scrotum.

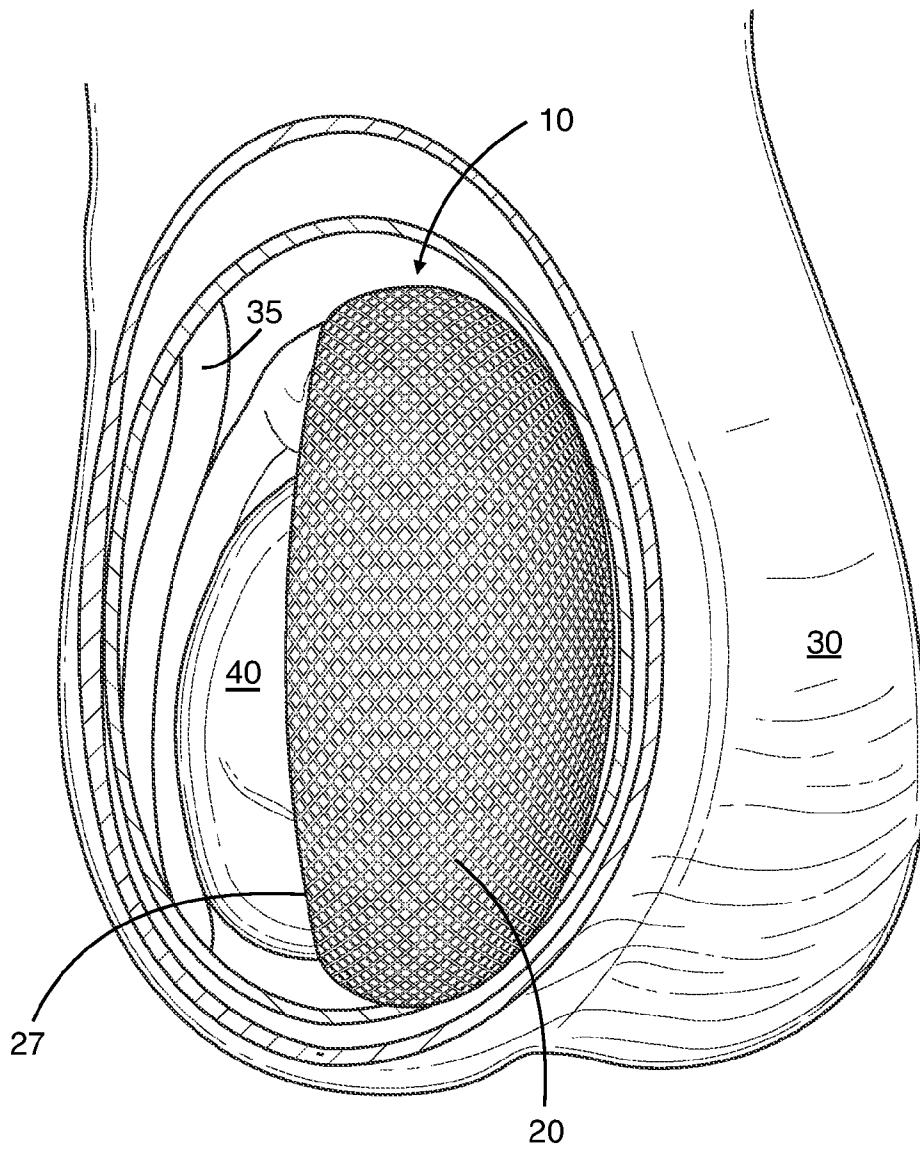


FIG. 1

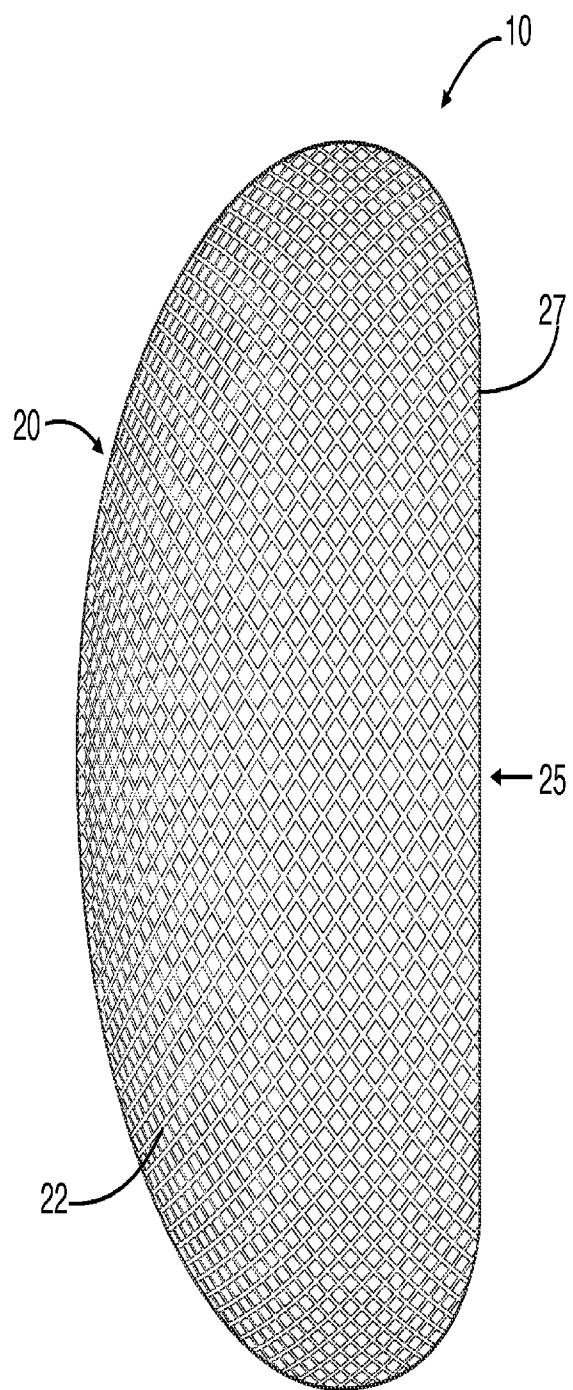


FIG. 2

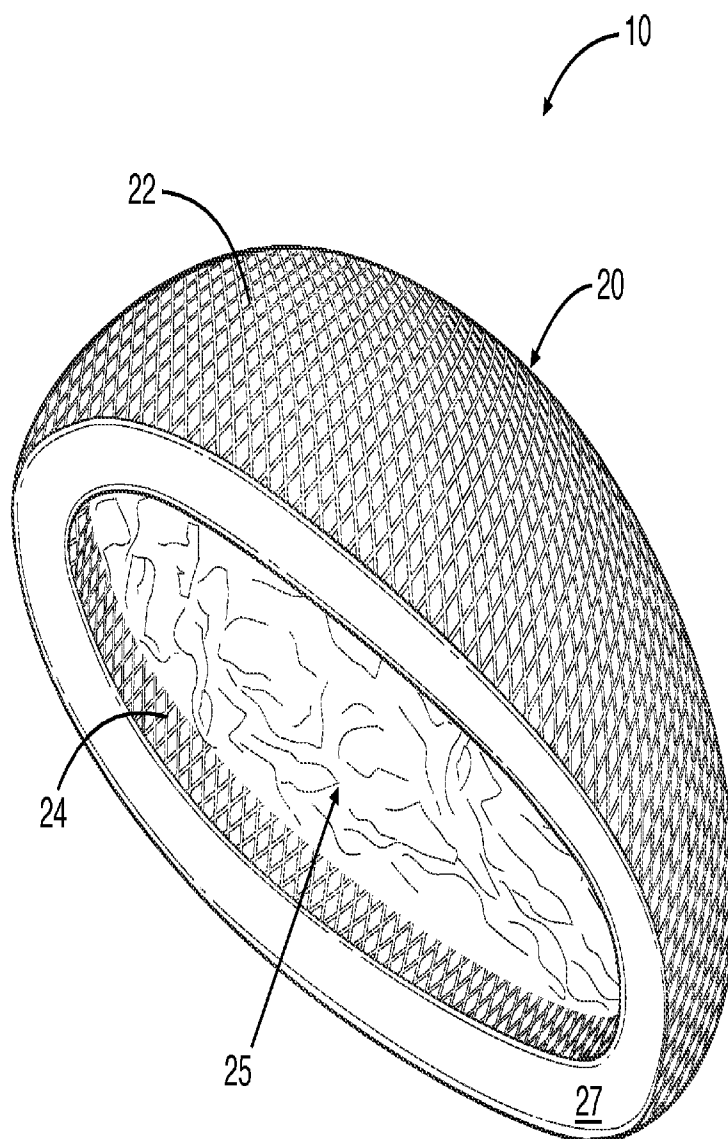


FIG. 3

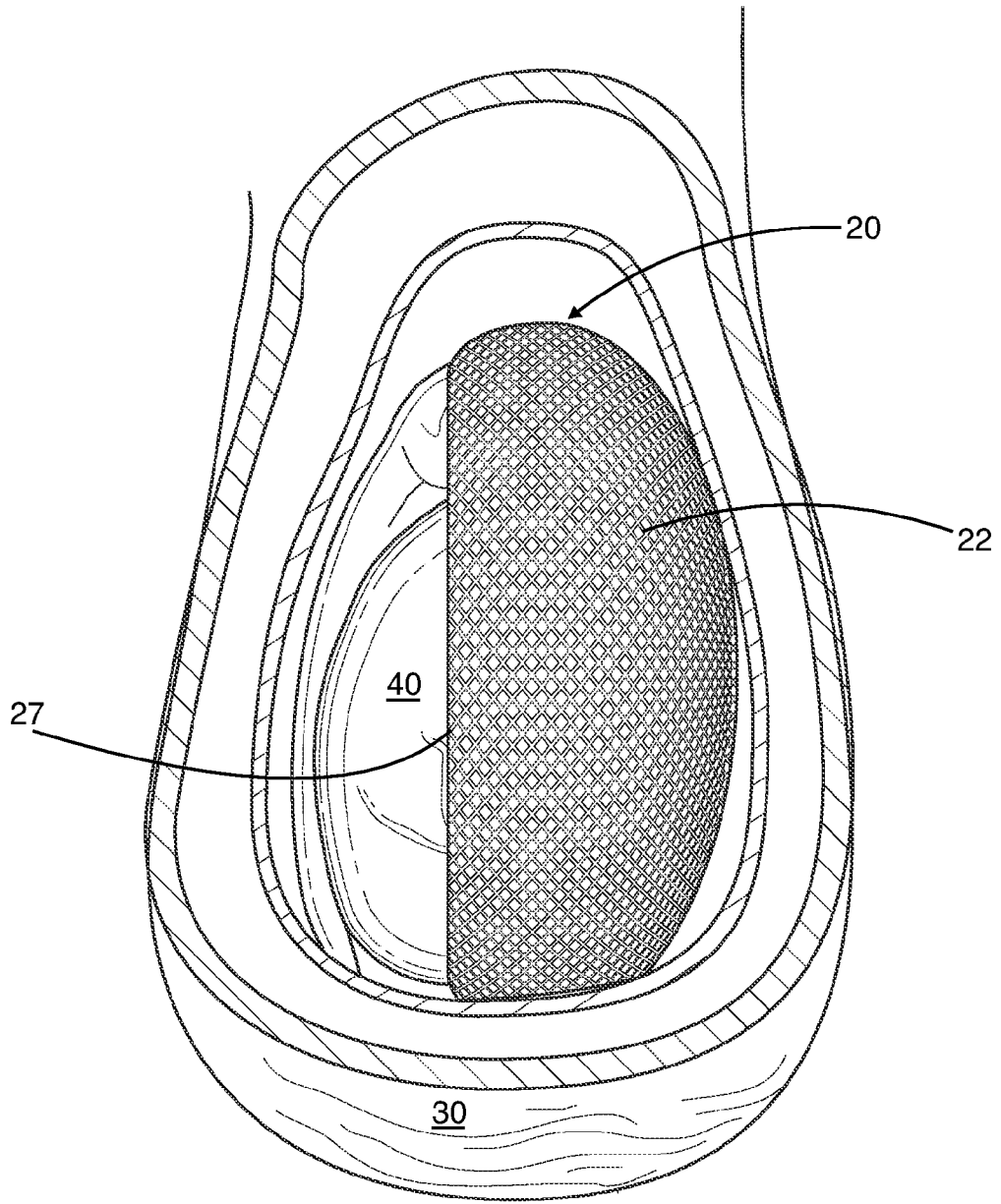


FIG. 4

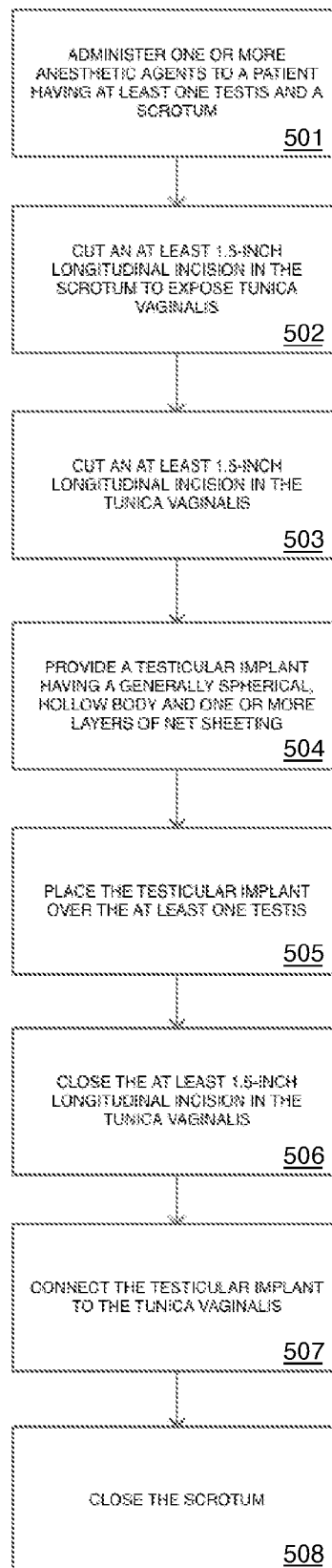


FIG. 5