

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
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In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court **Western District of Texas** on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.);

DOCKET NO. 1:23-cv-00460	DATE FILED 4/22/2023	U.S. DISTRICT COURT Western District of Texas
PLAINTIFF NEW AMSTERDAM, LLC		DEFENDANT MEDTRONIC, INC.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 US 6,916,483B2	7/12/2005	New Amsterdam LLC
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3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK PHILIP J. DEVLIN	(BY) DEPUTY CLERK 	DATE 04/26/2023
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Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
 Stylesheet Version v1.2

EPAS ID: PAT5474084

SUBMISSION TYPE:	NEW ASSIGNMENT	
NATURE OF CONVEYANCE:	SECURITY INTEREST	
CONVEYING PARTY DATA		
Name		Execution Date
BIODYNAMICS, LLC		12/29/2014
RECEIVING PARTY DATA		
Name:	FIRST COMMERCE BANK	
Street Address:	105 RIVER AVENUE	
City:	LAKEWOOD	
State/Country:	NEW JERSEY	
Postal Code:	08701	
PROPERTY NUMBERS Total: 19		
Property Type	Number	
Patent Number:	6916483	
Patent Number:	7621914	
Patent Number:	7695473	
Patent Number:	7824699	
Patent Number:	7833253	
Patent Number:	7922719	
Patent Number:	8080042	
Patent Number:	8083782	
Patent Number:	8088151	
Patent Number:	8128670	
Patent Number:	8241336	
Patent Number:	8403966	
Patent Number:	8444679	
Patent Number:	8460346	
Patent Number:	8597335	
Patent Number:	8790377	
Patent Number:	8915921	
Patent Number:	9289241	
Patent Number:	9814577	

CORRESPONDENCE DATA**Fax Number:** (732)363-6666

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 732-363-3333**Email:** LMANDEL@GMPLAW.NET**Correspondent Name:** LAWRENCE D. MANDEL**Address Line 1:** P.O. BOX 301**Address Line 4:** LAKEWOOD, NEW JERSEY 08701

ATTORNEY DOCKET NUMBER:	2447-01
NAME OF SUBMITTER:	LAWRENCE D. MANDEL
SIGNATURE:	/lawrencedmandel/
DATE SIGNED:	04/15/2019
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 7

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COMMERCIAL SECURITY AGREEMENT

Principal	Loan Date	Maturity	Loan No.	Call / Coll	Account	Office	Initials
\$2,999,999.00	12/29/2014	12/29/2016	1	3-500		DA	

References in the boxes above are for Lender's use only and do not limit the applicability of this document to any particular loan or item. Any item above containing "****" has been omitted due to text length limitations.

Grantor: Biodynamics, L.L.C.
MBD Medical, L.L.C.
84 Honeck Street
Englewood, NJ 07631

Lender: FIRST COMMERCE BANK
Lakewood
105 River Avenue
Lakewood, NJ 08701

DEFINITIONS. The following capitalized words and terms shall have the following meanings when used in this Agreement. Unless specifically stated to the contrary, all references to dollar amounts shall mean amounts in lawful money of the United States of America. Words and terms used in the singular shall include the plural, and the plural shall include the singular, as the context may require. Words and terms not otherwise defined in this Agreement shall have the meanings attributed to such terms in the Uniform Commercial Code:

Agreement. The word "Agreement" means this Commercial Security Agreement, as this Commercial Security Agreement may be amended or modified from time to time, together with all exhibits and schedules attached to this Commercial Security Agreement from time to time.

Borrower. The word "Borrower" means Biodynamics, L.L.C.; and MBD Medical, L.L.C. and includes all co-signers and co-makers signing the Note and all their successors and assigns.

Collateral. The word "Collateral" means all of Grantor's right, title and interest in and to all the Collateral as described in the Collateral Description section of this Agreement.

Default. The word "Default" means the Default set forth in this Agreement in the section titled "Default".

Environmental Laws. The words "Environmental Laws" mean any and all state, federal and local statutes, regulations and ordinances relating to the protection of human health or the environment, including without limitation the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. Section 9601, et seq. ("CERCLA"), the Superfund Amendments and Reauthorization Act of 1986, Pub. L. No. 99-499 ("SARA"), the Hazardous Materials Transportation Act, 49 U.S.C. Section 1801, et seq., the Resource Conservation and Recovery Act, 42 U.S.C. Section 6901, et seq., the New Jersey Industrial Site Recovery Act, NJSA Section 13:1K-6 ("ISRA"), the New Jersey Spill Compensation and Control Act, NJSA 58:10-23.11, et seq., or other applicable state or federal laws, rules, or regulations adopted pursuant thereto.

Event of Default. The words "Event of Default" mean any of the events of default set forth in this Agreement in the default section of this Agreement.

Grantor. The word "Grantor" means Biodynamics, L.L.C.; and MBD Medical, L.L.C..

Guarantor. The word "Guarantor" means any guarantor, surety, or accommodation party of any or all of the indebtedness.

Guaranty. The word "Guaranty" means the guaranty from Guarantor to Lender, including without limitation a guaranty of all or part of the Note.

Hazardous Substances. The words "Hazardous Substances" mean materials that, because of their quantity, concentration or physical, chemical or infectious characteristics, may cause or pose a present or potential hazard to human health or the environment when improperly used, treated, stored, disposed of, generated, manufactured, transported or otherwise handled. The words "Hazardous Substances" are used in their very broadest sense and include without limitation any and all hazardous or toxic substances, materials or waste as defined by or listed under the Environmental Laws. The term "Hazardous Substances" also includes, without limitation, petroleum and petroleum by-products or any fraction thereof and asbestos.

Indebtedness. The word "Indebtedness" means the indebtedness evidenced by the Note or Related Documents, including all principal and interest together with all other indebtedness and costs and expenses for which Grantor is responsible under this Agreement or under any of the Related Documents. Specifically, without limitation, Indebtedness includes the future advances set forth in the Future Advances provision, together with all interest thereon and all amounts that may be indirectly secured by the Cross-Collateralization provision of this Agreement.

Lender. The word "Lender" means FIRST COMMERCE BANK, its successors and assigns.

Note. The word "Note" means the Note dated December 29, 2014 and executed by Biodynamics, L.L.C.; and MBD Medical, L.L.C. in the principal amount of \$2,999,999.00, together with all renewals of, extensions of, modifications of, refinancings of, consolidations of, and substitutions for the note or credit agreement.

Property. The word "Property" means all of Grantor's right, title and interest in and to all the Property as described in the "Collateral Description" section of this Agreement.

Related Documents. The words "Related Documents" mean all promissory notes, credit agreements, loan agreements, environmental agreements, guaranties, security agreements, mortgages, deeds of trust, security deeds, collateral mortgages, and all other instruments, agreements and documents, whether now or hereafter existing, executed in connection with the Indebtedness.

THIS COMMERCIAL SECURITY AGREEMENT dated December 29, 2014, is made and executed between Biodynamics, L.L.C.; and MBD Medical, L.L.C. ("Grantor") and FIRST COMMERCE BANK ("Lender").

GRANT OF SECURITY INTEREST. For valuable consideration, Grantor grants to Lender a security interest in the Collateral to secure the Indebtedness and agrees that Lender shall have the rights stated in this Agreement with respect to the Collateral, in addition to all other rights which Lender may have by law.

COLLATERAL DESCRIPTION. The word "Collateral" as used in this Agreement means the following described property, whether now owned or hereafter acquired, whether now existing or hereafter arising, and wherever located, in which Grantor is giving to Lender a security interest for the payment of the Indebtedness and performance of all other obligations under the Note and this Agreement:

All Inventory and All Business Assets of Biodynamics, L.L.C. and MBD Medical, L.L.C. in a first lien position including but not limited to accounts, accounts receivable, inventory, goods, machinery, equipment, furniture, fixtures, chattel paper, instruments, documents, merchandise supplies, general intangibles, money securities, contract rights; All Intellectual property assets such as patents or patents applications, copyrights, trademarks, and proceeds including insurance proceeds and products thereof, now owned or hereafter acquired.

All patents applications, included but not limited to list (see Schedule A) attached to this UCC-1 Financing Statement and made a part hereof as if fully set forth herein, and all continuing patent applications (including, without limitation, continuation, continuation-in-part, and

COMMERCIAL SECURITY AGREEMENT (Continued)

In addition, the word "Collateral" also includes all the following, whether now owned or hereafter acquired, whether now existing or hereafter arising, and wherever located:

- (A) All accessions, attachments, accessories, tools, parts, supplies, replacements of and additions to any of the collateral described herein, whether added now or later.
- (B) All products and produce of any of the property described in this Collateral section.
- (C) All accounts, general intangibles, instruments, rents, monies, payments, and all other rights, arising out of a sale, lease, consignment or other disposition of any of the property described in this Collateral section.
- (D) All proceeds (including insurance proceeds) from the sale, destruction, loss, or other disposition of any of the property described in this Collateral section, and sums due from a third party who has damaged or destroyed the Collateral or from that party's insurer, whether due to judgment, settlement or other process.
- (E) All records and data relating to any of the property described in this Collateral section, whether in the form of a writing, photograph, microfilm, microfiche, or electronic media, together with all of Grantor's right, title, and interest in and to all computer software required to utilize, create, maintain, and process any such records or data on electronic media.

CROSS-COLLATERALIZATION. In addition to the Note, this Agreement secures all obligations, debts and liabilities, plus interest thereon, of Grantor to Lender, or any one or more of them, as well as all claims by Lender against Grantor or any one or more of them, whether now existing or hereafter arising, whether related or unrelated to the purpose of the Note, whether voluntary or otherwise, whether due or not due, direct or indirect, determined or undetermined, absolute or contingent, liquidated or unliquidated, whether Grantor may be liable individually or jointly with others, whether obligated as guarantor, surety, accommodation party or otherwise, and whether recovery upon such amounts may be or hereafter may become barred by any statute of limitations, and whether the obligation to repay such amounts may be or hereafter may become otherwise unenforceable.

FUTURE ADVANCES. In addition to the Note, this Agreement secures all future advances made by Lender to Grantor regardless of whether the advances are made a) pursuant to a commitment or b) for the same purposes.

RIGHT OF SETOFF. To the extent permitted by applicable law, Lender reserves a right of setoff in all Grantor's accounts with Lender (whether checking, savings, or some other account). This includes all accounts Grantor holds jointly with someone else and all accounts Grantor may open in the future. However, this does not include any IRA or Keogh accounts, or any trust accounts for which setoff would be prohibited by law. Grantor authorizes Lender, to the extent permitted by applicable law, to charge or setoff all sums owing on the indebtedness against any and all such accounts.

GRANTOR'S REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE COLLATERAL. With respect to the Collateral, Grantor represents and promises to Lender that:

Perfection of Security Interest. Grantor agrees to take whatever actions are requested by Lender to perfect and continue Lender's security interest in the Collateral. Upon request of Lender, Grantor will deliver to Lender any and all of the documents evidencing or constituting the Collateral, and Grantor will note Lender's interest upon any and all chattel paper and instruments if not delivered to Lender for possession by Lender. This is a continuing Security Agreement and will continue in effect even though all or any part of the indebtedness is paid in full and even though for a period of time Grantor may not be indebted to Lender.

Notices to Lender. Grantor will promptly notify Lender in writing at Lender's address shown above (or such other addresses as Lender may designate from time to time) prior to any (1) change in Grantor's name; (2) change in Grantor's assumed business name(s); (3) change in the management or in the members or managers of the limited liability company Grantor; (4) change in the authorized signer(s); (5) change in Grantor's principal office address; (6) change in Grantor's state of organization; (7) conversion of Grantor to a new or different type of business entity; or (8) change in any other aspect of Grantor that directly or indirectly relates to any agreements between Grantor and Lender. No change in Grantor's name or state of organization will take effect until after Lender has received notice.

No Violation. The execution and delivery of this Agreement will not violate any law or agreement governing Grantor or to which Grantor is a party, and its membership agreement does not prohibit any term or condition of this Agreement.

Enforceability of Collateral. To the extent the Collateral consists of accounts, chattel paper, or general intangibles, as defined by the Uniform Commercial Code, the Collateral is enforceable in accordance with its terms, is genuine, and fully complies with all applicable laws and regulations concerning form, content and manner of preparation and execution, and all persons appearing to be obligated on the Collateral have authority and capacity to contract and are in fact obligated as they appear to be on the Collateral. At the time any account becomes subject to a security interest in favor of Lender, the account shall be a good and valid account representing an undisputed, bona fide indebtedness incurred by the account debtor, for merchandise held subject to delivery instructions or previously shipped or delivered pursuant to a contract of sale, or for services previously performed by Grantor with or for the account debtor. So long as this Agreement remains in effect, Grantor shall not, without Lender's prior written consent, compromise, settle, adjust, or extend payment under or with regard to any such Accounts. There shall be no setoffs or counterclaims against any of the Collateral, and no agreement shall have been made under which any deductions or discounts may be claimed concerning the Collateral except those disclosed to Lender in writing.

Location of the Collateral. Except in the ordinary course of Grantor's business, Grantor agrees to keep the Collateral for to the extent the Collateral consists of intangible property such as accounts or general intangibles, the records concerning the Collateral at Grantor's address shown above or at such other locations as are acceptable to Lender. Upon Lender's request, Grantor will deliver to Lender in form satisfactory to Lender a schedule of real properties and Collateral locations relating to Grantor's operations, including without limitation the following: (1) all real property Grantor owns or is purchasing; (2) all real property Grantor is renting or leasing; (3) all storage facilities Grantor owns, rents, leases, or uses; and (4) all other properties where Collateral is or may be located.

Removal of the Collateral. Except in the ordinary course of Grantor's business, including the sales of inventory, Grantor shall not remove the Collateral from its existing location without Lender's prior written consent. To the extent that the Collateral consists of vehicles, or other titled property, Grantor shall not take or permit any action which would require application for certificates of title for the vehicles outside the State of New Jersey, without Lender's prior written consent. Grantor shall, whenever requested, advise Lender of the exact location of the Collateral.

Transactions Involving Collateral. Except for inventory sold or accounts collected in the ordinary course of Grantor's business, or as otherwise provided for in this Agreement, Grantor shall not sell, offer to sell, or otherwise transfer or dispose of the Collateral. While Grantor is not in default under this Agreement, Grantor may sell inventory, but only in the ordinary course of its business and only to buyers who qualify as a buyer in the ordinary course of business. A sale in the ordinary course of Grantor's business does not include a transfer in

COMMERCIAL SECURITY AGREEMENT
(Continued)

partial or total satisfaction of a debt or any bulk sale. Grantor shall not pledge, mortgage, encumber or otherwise permit the Collateral to be subject to any lien, security interest, encumbrance, or charge, other than the security interest provided for in this Agreement, without the prior written consent of Lender. This includes security interests even if junior in right to the security interests granted under this Agreement. Unless waived by Lender, all proceeds from any disposition of the Collateral (for whatever reason) shall be held in trust for Lender and shall not be commingled with any other funds; provided however, this requirement shall not constitute consent by Lender to any sale or other disposition. Upon receipt, Grantor shall immediately deliver any such proceeds to Lender.

Title. Grantor represents and warrants to Lender that Grantor holds good and marketable title to the Collateral, free and clear of all liens and encumbrances except for the lien of this Agreement. No financing statement covering any of the Collateral is on file in any public office other than those which reflect the security interest created by this Agreement or to which Lender has specifically consented. Grantor shall defend Lender's rights in the Collateral against the claims and demands of all other persons.

Repairs and Maintenance. Grantor agrees to keep and maintain, and to cause others to keep and maintain, the Collateral in good order, repair and condition at all times while this Agreement remains in effect. Grantor further agrees to pay when due all claims for work done on, or services rendered or material furnished in connection with the Collateral so that no lien or encumbrance may ever attach to or be filed against the Collateral.

Inspection of Collateral. Lender and Lender's designated representatives and agents shall have the right at all reasonable times to examine and inspect the Collateral wherever located.

Taxes, Assessments and Liens. Grantor will pay when due all taxes, assessments and liens upon the Collateral, its use or operation, upon this Agreement, upon any promissory note or notes evidencing the indebtedness, or upon any of the other Related Documents. Grantor may withhold any such payment or may elect to contest any lien if Grantor is in good faith conducting an appropriate proceeding to contest the obligation to pay and so long as Lender's interest in the Collateral is not jeopardized in Lender's sole opinion. If the Collateral is subjected to a lien which is not discharged within fifteen (15) days, Grantor shall deposit with Lender cash, a sufficient corporate surety bond or other security satisfactory to Lender in an amount adequate to provide for the discharge of the lien plus any interest, costs, attorneys' fees or other charges that could accrue as a result of foreclosure or sale of the Collateral. In any contest Grantor shall defend itself and Lender and shall satisfy any final adverse judgment before enforcement against the Collateral. Grantor shall name Lender as an additional obligee under any surety bond furnished in the contest proceedings. Grantor further agrees to furnish Lender with evidence that such taxes, assessments, and governmental and other charges have been paid in full and in a timely manner. Grantor may withhold any such payment or may elect to contest any lien if Grantor is in good faith conducting an appropriate proceeding to contest the obligation to pay and so long as Lender's interest in the Collateral is not jeopardized.

Compliance with Governmental Requirements. Grantor shall comply promptly with all laws, ordinances, rules and regulations of all governmental authorities, including without limitation all environmental laws, ordinances, rules and regulations, now or hereafter in effect, applicable to the ownership, production, disposition, or use of the Collateral, including all laws or regulations relating to the undue erosion of highly-erodible land or relating to the conversion of wetlands for the production of an agricultural product or commodity. Grantor may contest in good faith any such law, ordinance or regulation and withhold compliance during any proceeding, including appropriate appeals, so long as Lender's interest in the Collateral, in Lender's opinion, is not jeopardized.

Hazardous Substances. Grantor represents and warrants that the Collateral never has been, and never will be so long as this Agreement remains a lien on the Collateral, used in violation of any Environmental Laws or for the generation, manufacture, storage, transportation, treatment, disposal, release or threatened release of any Hazardous Substance. The representations and warranties contained herein are based on Grantor's due diligence in investigating the Collateral for Hazardous Substances. Grantor hereby (1) releases and waives any future claims against Lender for indemnity or contribution in the event Grantor becomes liable for cleanup or other costs under any Environmental Laws, and (2) agrees to indemnify, defend, and hold harmless Lender against any and all claims and losses resulting from a breach of this provision of this Agreement. This obligation to indemnify and defend shall survive the payment of the indebtedness and the satisfaction of this Agreement.

Maintenance of Casualty Insurance. Grantor shall procure and maintain all risks insurance, including without limitation fire, theft and liability coverage together with such other insurance as Lender may require with respect to the Collateral, in form, amounts, coverages and basis reasonably acceptable to Lender and issued by a company or companies reasonably acceptable to Lender. Grantor, upon request of Lender, will deliver to Lender from time to time the policies or certificates of insurance in form satisfactory to Lender, including stipulations that coverages will not be cancelled or diminished without at least thirty (30) days' prior written notice to Lender and not including any disclaimer of the insurer's liability for failure to give such a notice. Each insurance policy also shall include an endorsement providing that coverage in favor of Lender will not be impaired in any way by any act, omission or default of Grantor or any other person. In connection with all policies covering assets in which Lender holds or is offered a security interest, Grantor will provide Lender with such loss payable or other endorsements as Lender may require. If Grantor at any time fails to obtain or maintain any insurance as required under this Agreement, Lender may (but shall not be obligated to) obtain such insurance as Lender deems appropriate, including if Lender so chooses "single interest insurance," which will cover only Lender's interest in the Collateral.

Application of Insurance Proceeds. Grantor shall promptly notify Lender of any loss or damage to the Collateral, whether or not such casualty or loss is covered by insurance. Lender may make proof of loss if Grantor fails to do so within fifteen (15) days of the casualty. All proceeds of any insurance on the Collateral, including accrued proceeds thereon, shall be held by Lender as part of the Collateral. If Lender consents to repair or replacement of the damaged or destroyed Collateral, Lender shall, upon satisfactory proof of expenditure, pay or reimburse Grantor from the proceeds for the reasonable cost of repair or restoration. If Lender does not consent to repair or replacement of the Collateral, Lender shall retain a sufficient amount of the proceeds to pay all of the indebtedness, and shall pay the balance to Grantor. Any proceeds which have not been disbursed within six (6) months after their receipt and which Grantor has not committed to the repair or restoration of the Collateral shall be used to prepay the indebtedness.

Insurance Reserves. Lender may require Grantor to maintain with Lender reserves for payment of insurance premiums, which reserves shall be created by monthly payments from Grantor of a sum estimated by Lender to be sufficient to produce, at least fifteen (15) days before the premium due date, amounts at least equal to the insurance premiums to be paid. If fifteen (15) days before payment is due, the reserve funds are insufficient, Grantor shall upon demand pay any deficiency to Lender. The reserve funds shall be held by Lender as a general deposit and shall constitute a non-interest-bearing account which Lender may satisfy by payment of the insurance premiums required to be paid by Grantor as they become due. Lender does not hold the reserve funds in trust for Grantor, and Lender is not the agent of Grantor for payment of the insurance premiums required to be paid by Grantor. The responsibility for the payment of premiums shall remain Grantor's sole responsibility.

Insurance Reports. Grantor, upon request of Lender, shall furnish to Lender reports on each existing policy of insurance showing such information as Lender may reasonably request including the following: (1) the name of the insurer; (2) the risks insured; (3) the amount of the policy; (4) the property insured; (5) the then current value on the basis of which insurance has been obtained and the manner of determining that value; and (6) the expiration date of the policy. In addition, Grantor shall upon request by Lender (however not more

often than annually) have an independent appraiser satisfactory to Lender determine, as applicable, the cash value or replacement cost of the Collateral.

Financing Statements. Grantor authorizes Lender to file a UCC financing statement, or alternatively, a copy of this Agreement to perfect Lender's security interest. At Lender's request, Grantor additionally agrees to sign all other documents that are necessary to perfect, protect, and continue Lender's security interest in the Property. This includes making sure Lender is shown as the first and only security interest holder on the title covering the Property. Grantor will pay all filing fees, title transfer fees, and other fees and costs involved unless prohibited by law or unless Lender is required by law to pay such fees and costs. Grantor will promptly notify Lender of any change to Grantor's name or the name of any individual Grantor, any individual who is a partner for a Grantor, and any individual who is a trustee or settlor or trustor for a Grantor under this Agreement. Grantor will also promptly notify Lender of any change to the name that appears on the most recently issued, unexpired driver's license or state-issued identification card, any expiration of the most recently issued driver's license or state-issued identification card for Grantor or any individual for whom Grantor is required to provide notice regarding name changes.

GRANTOR'S RIGHT TO POSSESSION AND TO COLLECT ACCOUNTS. Until default and except as otherwise provided below with respect to accounts, Grantor may have possession of the tangible personal property and beneficial use of all the Collateral and may use it in any lawful manner not inconsistent with this Agreement or the Related Documents, provided that Grantor's right to possession and beneficial use shall not apply to any Collateral where possession of the Collateral by Lender is required by law to perfect Lender's security interest in such Collateral. Until otherwise notified by Lender, Grantor may collect any of the Collateral consisting of accounts. At any time and even though no Event of Default exists, Lender may exercise its rights to collect the accounts and to notify account debtors to make payments directly to Lender for application to the Indebtedness. If Lender at any time has possession of any Collateral, whether before or after an Event of Default, Lender shall be deemed to have exercised reasonable care in the custody and preservation of the Collateral if Lender takes such action for that purpose as Grantor shall request or as Lender, in Lender's sole discretion, shall deem appropriate under the circumstances, but failure to honor any request by Grantor shall not of itself be deemed to be a failure to exercise reasonable care. Lender shall not be required to take any steps necessary to preserve any rights in the Collateral against prior parties, nor to protect, preserve or maintain any security interest given to secure the Indebtedness.

LENDER'S EXPENDITURES. If any action or proceeding is commenced that would materially affect Lender's interest in the Collateral or if Grantor fails to comply with any provision of this Agreement or any Related Documents, including but not limited to Grantor's failure to discharge or pay when due any amounts Grantor is required to discharge or pay under this Agreement or any Related Documents, Lender on Grantor's behalf may (but shall not be obligated to) take any action that Lender deems appropriate, including but not limited to discharging or paying all taxes, liens, security interests, encumbrances and other claims, at any time levied or placed on the Collateral and paying all costs for insuring, maintaining and preserving the Collateral. All such expenditures incurred or paid by Lender for such purposes will then bear interest at the rate charged under the Note from the date incurred or paid by Lender to the date of repayment by Grantor. All such expenses will become a part of the Indebtedness and, at Lender's option, will (A) be payable on demand; (B) be added to the balance of the Note and be apportioned among and be payable with any installment payments to become due during either (1) the term of any applicable insurance policy; or (2) the remaining term of the Note; or (C) be treated as a balloon payment which will be due and payable at the Note's maturity. The Agreement also will secure payment of these amounts. Such right shall be in addition to all other rights and remedies to which Lender may be entitled upon Default.

DEFAULT. Each of the following shall constitute an Event of Default under this Agreement:

Payment Default. Grantor fails to make any payment when due under the Indebtedness.

Environmental Default. Failure of any party to comply with or perform when due any term, obligation, covenant or condition contained in any environmental agreement executed in connection with any Indebtedness.

Other Defaults. Grantor fails to comply with or to perform any other term, obligation, covenant or condition contained in this Agreement or in any of the Related Documents or to comply with or to perform any term, obligation, covenant or condition contained in any other agreement between Lender and Grantor.

Default in Favor of Third Parties. Any guarantor or Grantor defaults under any loan, extension of credit, security agreement, purchase or sales agreement, or any other agreement, in favor of any other creditor or person that may materially affect any of any guarantor's or Grantor's property or ability to perform their respective obligations under this Agreement or any of the Related Documents.

False Statements. Any warranty, representation or statement made or furnished to Lender by Grantor or on Grantor's behalf under this Agreement or the Related Documents is false or misleading in any material respect, either now or at the time made or furnished or becomes false or misleading at any time thereafter.

Defective Collateralization. This Agreement or any of the Related Documents ceases to be in full force and effect (including failure of any Related Documents to create a valid and perfected security interest or lien) at any time and for any reason.

Insolvency. The dissolution of Grantor (regardless of whether election to continue is made), any member withdraws from the limited liability company, or any other termination of Grantor's existence as a going business or the death of any member, the insolvency of Grantor, the appointment of a receiver for any part of Grantor's property, any assignment for the benefit of creditors, any type of creditor workout, or the commencement of any proceeding under any bankruptcy or insolvency laws by or against Grantor.

Creditor or Forfeiture Proceedings. Commencement of foreclosure or forfeiture proceedings, whether by judicial proceeding, self-help, repossession or any other method, by any creditor of Grantor or by any governmental agency against any collateral securing the Indebtedness. This includes a garnishment of any of Grantor's accounts, including deposit accounts, with Lender. However, this Event of Default shall not apply if there is a good faith dispute by Grantor as to the validity or reasonableness of the claim which is the basis of the creditor or forfeiture proceeding and if Grantor gives Lender written notice of the creditor or forfeiture proceeding and deposits with Lender monies or a surety bond for the creditor or forfeiture proceeding, in an amount determined by Lender, in its sole discretion, as being an adequate reserve or bond for the dispute.

Events Affecting Guarantor. Any of the preceding events occurs with respect to any Guarantor of any of the Indebtedness or Guarantor dies or becomes incompetent or revokes or disputes the validity of, or liability under, any Guaranty of the Indebtedness.

Adverse Change. A material adverse change occurs in Grantor's financial condition, or Lender believes the prospect of payment or performance of the Indebtedness is impaired.

Cure Provisions. If any default, other than a default in payment is curable and if Grantor has not been given a notice of a breach of the same provision of this Agreement within the preceding twelve (12) months, it may be cured if Grantor, after Lender sends written notice to Grantor demanding cure of such default: (1) cures the default within thirty (30) days; or (2) if the cure requires more than thirty (30) days, immediately initiates steps which Lender deems in Lender's sole discretion to be sufficient to cure the default and thereafter continues and completes all reasonable and necessary steps sufficient to produce compliance as soon as reasonably practical.

COMMERCIAL SECURITY AGREEMENT (Continued)

RIGHTS AND REMEDIES ON DEFAULT. If an Event of Default occurs under this Agreement, at any time thereafter, Lender shall have all the rights of a secured party under the New Jersey Uniform Commercial Code. In addition and without limitation, Lender may exercise any one or more of the following rights and remedies:

Accelerate Indebtedness. Lender may declare the entire Indebtedness, including any prepayment penalty which Grantor would be required to pay, immediately due and payable, without notice of any kind to Grantor.

Assemble Collateral. Lender may require Grantor to deliver to Lender all or any portion of the Collateral and any and all certificates of title and other documents relating to the Collateral. Lender may require Grantor to assemble the Collateral and make it available to Lender at a place to be designated by Lender. Lender also shall have full power to enter upon the property of Grantor to take possession of and remove the Collateral. If the Collateral contains other goods not covered by this Agreement at the time of repossession, Grantor agrees Lender may take such other goods, provided that Lender makes reasonable efforts to return them to Grantor after repossession.

Sell the Collateral. Lender shall have full power to sell, lease, transfer, or otherwise deal with the Collateral or proceeds thereof in Lender's own name or that of Grantor. Lender may sell the Collateral at public auction or private sale. Unless the Collateral threatens to decline speedily in value or is of a type customarily sold on a recognized market, Lender will give Grantor, and other persons as required by law, reasonable notice of the time and place of any public sale, or the time after which any private sale or any other disposition of the Collateral is to be made. However, no notice need be provided to any person who, after Event of Default occurs, enters into and authenticates an agreement waiving that person's right to notification of sale. The requirements of reasonable notice shall be met if such notice is given at least ten (10) days before the time of the sale or disposition. All expenses relating to the disposition of the Collateral, including without limitation the expenses of retaking, holding, insuring, preparing for sale and selling the Collateral, shall become a part of the Indebtedness secured by this Agreement and shall be payable on demand, with interest at the Note rate from date of expenditure until repaid.

Appoint Receiver. Lender shall have the right to have a receiver appointed to take possession of all or any part of the Collateral, with the power to protect and preserve the Collateral, to operate the Collateral preceding foreclosure or sale, and to collect the rents from the Collateral and apply the proceeds, over and above the cost of the receivership, against the Indebtedness. The receiver may serve without bond if permitted by law. Lender's right to the appointment of a receiver shall exist whether or not the apparent value of the Collateral exceeds the Indebtedness by a substantial amount. Employment by Lender shall not disqualify a person from serving as a receiver.

Collect Revenues, Apply Accounts. Lender, either itself or through a receiver, may collect the payments, rents, income, and revenues from the Collateral. Lender may at any time in Lender's discretion transfer any Collateral into Lender's own name or that of Lender's nominee and receive the payments, rents, income, and revenues therefrom and hold the same as security for the Indebtedness or apply it to payment of the Indebtedness in such order of preference as Lender may determine. Insofar as the Collateral consists of accounts, general intangibles, insurance policies, instruments, chattel paper, choses in action, or similar property, Lender may demand, collect, receipt for, settle, compromise, adjust, sue for, foreclose, or realize on the Collateral as Lender may determine, whether or not Indebtedness or Collateral is then due. For these purposes, Lender may, on behalf of and in the name of Grantor, receive, open and dispose of mail addressed to Grantor; change any address to which mail and payments are to be sent; and endorse notes, checks, drafts, money orders, documents of title, instruments and items pertaining to payment, shipment, or storage of any Collateral. To facilitate collection, Lender may notify account debtors and obligors on any Collateral to make payments directly to Lender.

Other Rights and Remedies. Lender shall have all the rights and remedies of a secured creditor under the provisions of the Uniform Commercial Code, as may be amended from time to time. In addition, Lender shall have and may exercise any or all other rights and remedies it may have available at law, in equity, or otherwise.

Election of Remedies. Except as may be prohibited by applicable law, all of Lender's rights and remedies, whether evidenced by this Agreement, the Related Documents, or by any other writing, shall be cumulative and may be exercised singularly or concurrently. Election by Lender to pursue any remedy shall not exclude pursuit of any other remedy, and an election to make expenditures or to take action to perform an obligation of Grantor under this Agreement, after Grantor's failure to perform, shall not affect Lender's right to declare a default and exercise its remedies.

HETER ISKA AGREEMENT. If applicable (as per First Commerce Bank's Heter Iska Policy), this loan shall be governed by the terms of First Commerce Bank's Heter Iska. Refer to the Heter Iska Agreement dated December 29, 2014.

MISCELLANEOUS PROVISIONS. The following miscellaneous provisions are a part of this Agreement:

Amendments. This Agreement, together with any Related Documents, constitutes the entire understanding and agreement of the parties as to the matters set forth in this Agreement. No alteration of or amendment to this Agreement shall be effective unless given in writing and signed by the party or parties sought to be charged or bound by the alteration or amendment.

Attorneys' Fees; Expenses. Grantor agrees to pay upon demand all of Lender's costs and expenses, including Lender's attorneys' fees and Lender's legal expenses, incurred in connection with the enforcement of this Agreement. Lender may hire or pay someone else to help enforce this Agreement, and Grantor shall pay the costs and expenses of such enforcement. Costs and expenses include Lender's attorneys' fees and legal expenses whether or not there is a lawsuit, including attorneys' fees and legal expenses for bankruptcy proceedings (including efforts to modify or vacate any automatic stay or injunction), appeals, and any anticipated post-judgment collection services. Grantor also shall pay all court costs and such additional fees as may be directed by the court.

Caption Headings. Caption headings in this Agreement are for convenience purposes only and are not to be used to interpret or define the provisions of this Agreement.

Governing Law. This Agreement will be governed by federal law applicable to Lender and, to the extent not preempted by federal law, the laws of the State of New Jersey without regard to its conflicts of law provisions. This Agreement has been accepted by Lender in the State of New Jersey.

Choice of Venue. If there is a lawsuit, Grantor agrees upon Lender's request to submit to the jurisdiction of the courts of Ocean County, State of New Jersey.

Joint and Several Liability. All obligations of Grantor under this Agreement shall be joint and several, and all references to Grantor shall mean each and every Grantor. This means that each Grantor signing below is responsible for all obligations in this Agreement. Where any one or more of the parties is a corporation, partnership, limited liability company or similar entity, it is not necessary for Lender to inquire into the powers of any of the officers, directors, partners, members, or other agents acting or purporting to act on the entity's behalf, and any obligations made or created in reliance upon the professed exercise of such powers shall be guaranteed under this Agreement.

No Waiver by Lender. Lender shall not be deemed to have waived any rights under this Agreement unless such waiver is given in writing and signed by Lender. No delay or omission on the part of Lender in exercising any right shall operate as a waiver of such right or any other right. A waiver by Lender of a provision of this Agreement shall not prejudice or constitute a waiver of Lender's right otherwise to demand strict compliance with that provision or any other provision of this Agreement. No prior waiver by Lender, nor any course of

dealing between Lender and Grantor, shall constitute a waiver of any of Lender's rights or of any of Grantor's obligations as to any future transactions. Whenever the consent of Lender is required under this Agreement, the granting of such consent by Lender in any instance shall not constitute continuing consent to subsequent instances where such consent is required and in all cases such consent may be granted or withheld in the sole discretion of Lender.

Notices. Any notice required to be given under this Agreement shall be given in writing, and shall be effective when actually delivered, when actually received by telefacsimile (unless otherwise required by law), when deposited with a nationally recognized overnight courier, or, if mailed, when deposited in the United States mail, as first class, certified or registered mail postage prepaid, directed to the addresses shown near the beginning of this Agreement. Any party may change its address for notices under this Agreement by giving formal written notice to the other parties, specifying that the purpose of the notice is to change the party's address. For notice purposes, Grantor agrees to keep Lender informed at all times of Grantor's current address. Unless otherwise provided or required by law, if there is more than one Grantor, any notice given by Lender to any Grantor is deemed to be notice given to all Grantors.

Power of Attorney. Grantor hereby appoints Lender as Grantor's irrevocable attorney-in-fact for the purpose of executing any documents necessary to perfect, amend, or to continue the security interest granted in this Agreement or to demand termination of filings of other secured parties. Lender may at any time, and without further authorization from Grantor, file a carbon, photographic or other reproduction of any financing statement or of this Agreement for use as a financing statement. Grantor will reimburse Lender for all expenses for the perfection and the continuation of the perfection of Lender's security interest in the Collateral.

Severability. If a court of competent jurisdiction finds any provision of this Agreement to be illegal, invalid, or unenforceable as to any person or circumstance, that finding shall not make the offending provision illegal, invalid, or unenforceable as to any other person or circumstance. If feasible, the offending provision shall be considered modified so that it becomes legal, valid and enforceable. If the offending provision cannot be so modified, it shall be considered deleted from this Agreement. Unless otherwise required by law, the illegality, invalidity, or unenforceability of any provision of this Agreement shall not affect the legality, validity or enforceability of any other provision of this Agreement.

Successors and Assigns. Subject to any limitations stated in this Agreement on transfer of Grantor's interest, this Agreement shall be binding upon and inure to the benefit of the parties, their successors and assigns. If ownership of the Collateral becomes vested in a person other than Grantor, Lender, without notice to Grantor, may deal with Grantor's successors with reference to this Agreement and the indebtedness by way of forbearance or extension without releasing Grantor from the obligations of this Agreement or liability under the indebtedness.

Survival of Representations and Warranties. All representations, warranties, and agreements made by Grantor in this Agreement shall survive the execution and delivery of this Agreement, shall be continuing in nature, and shall remain in full force and effect until such time as Grantor's indebtedness shall be paid in full.

Time is of the Essence. Time is of the essence in the performance of this Agreement.

Waive Jury. All parties to this Agreement hereby waive the right to any jury trial in any action, proceeding, or counterclaim brought by any party against any other party.

GRANTOR HAS READ AND UNDERSTOOD ALL THE PROVISIONS OF THIS COMMERCIAL SECURITY AGREEMENT AND AGREES TO ITS TERMS. THIS AGREEMENT IS DATED DECEMBER 29, 2014.

GRANTOR:

BIODYNAMICS, L.L.C.

By:

Jane A. Grinch, President of Biodynamics, L.L.C.

By:

Paul S. Starr, Chief Financial Officer of Biodynamics, L.L.C.

MBD MEDICAL, L.L.C.

BIODYNAMICS, L.L.C., Managing Member of MBD Medical, L.L.C.

By:

Jane A. Grinch, President of Biodynamics, L.L.C.

By:

Paul S. Starr, Chief Financial Officer of Biodynamics, L.L.C.

BioDynamics LLC			
United States Patents List			
	Patent		Issue
	Number	Description/Title	Date
1	6,916,483 B2	Bioabsorbable Plugs Containing Drugs	07/12/05
2	7,621,914 B2	Adjustable Bone Plate	11/24/09
3	7,695,473 B2	Adjustable Bone Plate	04/13/10
4	7,824,699 B2	Implantable Prosthetic Devices Containing Timed Release Therapeutic Agents	11/02/10
5	7,833,253 B2	Craniotomy Closures and Plugs	11/16/10
6	7,922,719 B2	Adjustable Angle Pawl Handle for Surgical Instruments	04/12/11
7	8,080,042 B2	Craniotomy Closures and Plugs	12/20/11
8	8,083,782 B2	Craniotomy Closures and Plugs	12/27/11
9	8,088,151 B2	Craniotomy Closures and Plugs	01/03/12
10	8,128,670 B2	Surgical Expansion Fasteners	03/06/12
11	8,241,336 B2	Craniotomy Closure System	08/14/12
12	8,403,966 B2	Clavicle Plate and Screws	03/26/13
13	8,444,679 B2	Clavicle Plate and Screws	05/21/13
14	8,460,346 B2	Craniotomy Closures	06/11/13
15	8,597,335 B2	Craniotomy Closures and Plugs	12/03/13
16	8,790,377 B2	Clavicle Plate and Screws	07/29/14
17	8,915,921 B2	Autologous Bone Harvest During Osteotomy and Bond Drilling Procedures	12/23/14
18	9,289,241 B2	Craniotomy Closures	03/22/16
19	9,814,577 B2	Implantable Mesh for Musculoskeletal Trauma, Orthopedic Reconstruction and Soft Tissue Repair	11/14/17



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



Bib Data Sheet

CONFIRMATION NO. 2385

SERIAL NUMBER 10/200,355	FILING OR 371(c) DATE 07/22/2002 RULE	CLASS 424	GROUP ART UNIT 1615	ATTORNEY DOCKET NO. 02RAL1	
APPLICANTS James Ralph, Seaside Park, NJ; Steve Tatar, Montville, NJ;					
** CONTINUING DATA *****					
** FOREIGN APPLICATIONS *****					
IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** SMALL ENTITY ** ** 08/20/2002					
Foreign Priority claimed ☐ yes ☐ no 35 USC 119 (a-d) conditions ☐ yes ☐ no ☐ Met after met Allowance Verified and Acknowledged _____ Examiner's Signature Initials		STATE OR COUNTRY NJ	SHEETS DRAWING 2	TOTAL CLAIMS 9	INDEPENDENT CLAIMS 2
ADDRESS 23526					
TITLE BIOABSORBABLE PLUGS CONTAINING DRUGS					
FILING FEE RECEIVED 670	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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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
10/200,355	07/22/2002	James Ralph	02RAL1

23526
NORRIS MCLAUGHLIN & MARCUS, P.A.
P O BOX 1018
SOMERVILLE, NJ 08876

CONFIRMATION NO. 2385



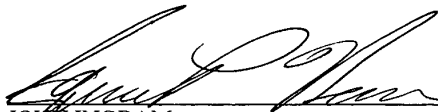
OC00000016242012

Date Mailed: 06/09/2005

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/23/2005.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.


JOHN INGRAM
FUBS Q-

OFFICE COPY



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/200,355	07/22/2002	James Ralph	02RAL1

Nancy A. Bird
 231 Walton Avenue
 So. Orange, NJ 07079

CONFIRMATION NO. 2385



OC000000016241999

Date Mailed: 06/09/2005

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/23/2005.

- The Power of Attorney to you in this application has been revoked by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record(37 CFR 1.33).


 JOHN INGRAM
 PUBS ()-

OFFICE COPY



05-24-05

B

1615, 150

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

JAMES D. RALPH, et al.

Serial No.: 10/200,355

Filed: July 22, 2002

For: BIOABSORBABLE PLUGS
CONTAINING DRUGS

Group Art Unit: 1615

Examiner: Sheikh, Humera N.

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

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label No. EV 570054106 US

Date of Deposit: May 23, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 2231301459

Print Name: Carolyn P. Stanton

Signature: *Carolyn P. Stanton*

TRANSMITTAL LETTER

Sir:

Enclosed herewith for filing in the United States Patent and Trademark Office are the following:

1. Form PTO/SB/82 Revocation of Power of Attorney with New Power of Attorney and Change of Correspondence Address.
2. Statement under 37 CFR 3.73(b)
3. Copy of Assignment of Patent Application from James Ralph and Steven Tatar to OsteoTools, LLC, with Recordation Form Cover Sheet.
4. Copy of Assignment from OsteoTools, LLC to BioDynamics, LLC, with Recordation Form Cover Sheet.

The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 14-1263. A duplicate copy of this paper is enclosed.

Respectfully submitted,



William R. Robinson
Registration No. 27,224

Date: May 23, 2005

Norris, McLaughlin & Marcus, P.A.
P.O. Box 1018
721 Route 202-206
Somerville, NJ 08876-1018
(908) 722-0700

104084-010



PTO/SB/82 (04-05)

Approved for use through 11/30/2005. OMB 0651-0035

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.

**REVOCATION OF POWER OF
ATTORNEY WITH
NEW POWER OF ATTORNEY
AND
CHANGE OF CORRESPONDENCE ADDRESS**

Application Number	10/200,355
Filing Date	July 22, 2002
First Named Inventor	Ralph, James
Art Unit	1615
Examiner Name	Sheikh, Humera N.
Attorney Docket Number	104084-010

I hereby revoke all previous powers of attorney given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint the practitioners associated with the Customer Number: 23526

☒ Please change the correspondence address for the above-identified application to:

☒ The address associated with
Customer Number:

23526

OR

☐ Firm or
Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

SIGNATURE of Applicant or Assignee of Record

Signature

Name

James D. Ralph, Vice President, BioDynamics, LLC (Assignee)

Date

May 19, 2005

Telephone

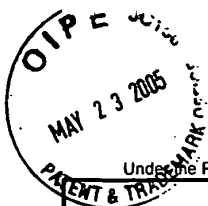
908-722-0700

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.36. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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



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.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: James Ralph, et al.

Application No./Patent No.: 10/200,355 Filed/Issue Date: July 22, 2002

Entitled: BIOABSORBABLE PLUGS CONTAINING DRUGS

BioDynamics, LLC, a limited liability company
(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by percentage) of its ownership interest is _____ %

in the patent application/patent identified above by virtue of either:

A ☐ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

OR

B ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: James Ralph and Steven Tatar To: OsteoTools, LLC
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached. Copy attached.

2. From: OsteoTools, LLC To: BioDynamics, LLC
The document was recorded in the United States Patent and Trademark Office at Reel 015996, Frame 0335, or for which a copy thereof is attached. Copy attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

James D. Ralph
Signature

James D. Ralph

Printed or Typed Name

Vice President

Title

May 19, 2005

Date

908-722-0700

Telephone Number

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. 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.



Law Offices of Nancy A. Bird
231 Walton Avenue, So. Orange, N.J. 07079
E-mail: nancyalicebird@aol.com
Phone: (973)-761-0714
Fax: (973)-761-0535

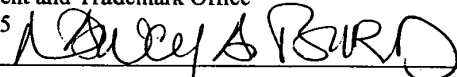
DATE: April 2, 2005
TO: United States Patent and Trademark Office
Assignment Recordation Services
RE: Application Serial No. 10/200,355
FAX NO.: (703) 306-5995
FROM: Nancy A. Bird
RE DOCKET #: JR1

Total pages (including cover): 4
Assignment (one page)
Recordation Form Cover Sheet (one page)
Credit Card Payment Form (one page)

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence, consisting of
Cover Sheet (one page), Assignment (one page)
Recordation Form Cover Sheet (one page)
Credit Card Payment Form (one page)
is being facsimile transmitted to the
United States Patent and Trademark Office
on April 2, 2005

Signature


NANCY A. BIRD

Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of transmission, or this certificate must identify each submitted paper.

USPTO fax cover Recordation Assignment to OsteoTools

RECORDATION FORM COVER SHEET
PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

1. Name of conveying party(ies)

James Ralpj & Steven Tatar

Additional name(s) of conveying party(ies) attached? ☒ Yes ☐ No

3. Nature of conveyance/Execution Date(s):

Execution Date(s) June, 30, 2003

- ☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Joint Research Agreement
☐ Government Interest Assignment
☐ Executive Order 9424, Confirmatory License
☐ Other _____

2. Name and address of receiving party(ies)

Name: OsteoTools, LLC

Internal Address: _____

Street Address: 1 University Plaza

City: Hackensack

State: New Jersey

Country: US Zip: 07601

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application or patent number(s):

A. Patent Application No.(s)
10/200,355

☐ This document is being filed together with a new application.
B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address to whom correspondence concerning document should be mailed:

Name: Jane Grinch

Internal Address: Suite 405

Street Address: 1 University Plaza

City: Hackensack

State: New Jersey Zip: 07601

Phone Number: 201-489-2992

Fax Number: 201-489-0442

Email Address: jgrinch@cowengrinch.com

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 1.21(h) & 3.41) \$ 100.00

- ☒ Authorized to be charged by credit card
☐ Authorized to be charged to deposit account
☐ Enclosed
☐ None required (government interest not affecting title)

8. Payment Information

a. Credit Card Last 4 Numbers _____
Expiration Date _____

b. Deposit Account Number _____

Authorized User Name _____

9. Signature:

Signature

Date

Nancy A. Bird

Name of Person Signing

Total number of pages including cover sheet, attachments, and documents:

2

Documents to be recorded (including cover sheet) should be faxed to (703) 306-5995, or mailed to:
Mail Stop Assignment Recordation Services, Director of the USPTO, P.O.Box 1450, Alexandria, V.A. 22313-1450

*Attached
Confidential*

ASSIGNMENT OF PATENT APPLICATION + Information Docket Number JR1

Whereas we, James Ralph of Seaside Park, New Jersey, & Steven Tatar of Montville, New Jersey, hereafter referred to as applicants, have invented certain new and useful improvements in BIOABSORBABLE PLUGS CONTAINING DRUGS for which an application for a United States Patent was filed on July 22, 2002 Application Number 10/200,355, and

Whereas, OsteoTools, LLC, here referred to "assignee" whose mailing address is 1 University Plaza Hackensack, N.J. is desirous of acquiring the entire right, title and interest in the same;

Now, therefore, in consideration of the sum of one dollar (\$ 1.00), the receipt whereof is acknowledged, and other good and valuable consideration, We, the applicants, by these presents do sell, assign and transfer unto said assignee the full and exclusive right to the said invention in the United States and the entire rights, title and interest in and to any and all Patents which may be granted therefore in the United States Patent to said assignee, of the entire right, title and interest in and to any and all Patents which may be granted therefore in the United States, We hereby authorize and request the Director of the U.S. Patent and Trademark Office to issue said United States Patent to said assignee, of the entire right, title, and interest in and to the same, for his sole use and behoof; and for the use and behoof of his legal representatives, to the full end of the term for which said Patent may be granted, as fully and entirely as the same would have been held by me had this assignment and sale not been made.

Executed this 30 day of June, 2003 at First Union Bank
State of NJ SS: (Signature) [Signature]
County of OCEAN

Before me personally appeared said James Ralph and acknowledged the foregoing instrument to be his free act and deed this ___ day of June, 2003.
Seal

JOHN AMATO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires Feb. 21, 2006

Executed this 30 day of June, 2003 at First Union Bank
State of NJ SS: (Signature) Steve Tatar
County of OCEAN

Before me personally appeared said Steve Tatar and acknowledged the foregoing instrument to be his free act and deed this ___ day of June, 2003.
Seal

JOHN AMATO
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires Feb. 21, 2006

A:\OsteoTools\ASSIGNMENT OF PATENT APPLICATION\Docket Number JR1.doc



Law Offices of Nancy A. Bird
231 Walton Avenue, So. Orange, N.J. 07079
E-mail: nancyalicebird@aol.com
Phone: (973)-761-0714
Fax: (973)-761-0535

DATE: April 2, 2005

TO: United States Patent and Trademark Office
Assignment Recordation Services

RE: Application Serial No. 10/200,355

FAX NO.: (703) 306-5995

FROM: Nancy A. Bird

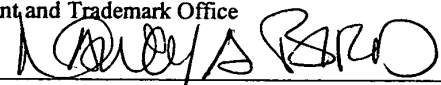
RE DOCKET #: JR1

Total pages (including cover): 4
Assignment (one page)
Recordation Form Cover Sheet (one page)
Credit Card Payment Form (one page)

Certificate of Transmission under 37 CFR 1.8

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NANCY A. BIRD

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USPTO fax cover Recordation Assignment to BioDynamics

RECORDATION FORM COVER SHEET
PATENTS ONLY

To the Director of the U.S. Patent and Trademark Office: Please record the attached documents or the new address(es) below.

1. Name of conveying party(ies)

OsteoTools, LLC

2. Name and address of receiving party(ies)

Name: BioDynamics, LLC

Internal Address: _____

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance/Execution Date(s):

Execution Date(s) April 1, 2005

- ☒ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Joint Research Agreement
☐ Government Interest Assignment
☐ Executive Order 9424, Confirmatory License
☐ Other _____

Street Address: 84 Honeck Street

City: Englewood

State: New Jersey

Country: US

Zip: 07631

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application or patent number(s):

☐ This document is being filed together with a new application.

A. Patent Application No.(s)
10/200,355

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address to whom correspondence concerning document should be mailed:

Name: Jane Grinch

Internal Address: Suite 405

Street Address: 1 University Plaza

City: Hackensack

State: New Jersey Zip: 07601

Phone Number: 201-489-2992

Fax Number: 201-489-0442

Email Address: jgrinch@cowengrinch.com

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 1.21(h) & 3.41) \$100.00

- ☒ Authorized to be charged by credit card
☐ Authorized to be charged to deposit account
☒ Enclosed
☐ None required (government interest not affecting title)

8. Payment Information

a. Credit Card Last 4 Numbers _____
Expiration Date _____

b. Deposit Account Number _____

Authorized User Name _____

9. Signature:

Nancy A. Bird
Signature

4-2-2005
Date

Nancy A. Bird

Name of Person Signing

Total number of pages including cover sheet, attachments, and documents:

2

Documents to be recorded (including cover sheet) should be faxed to (703) 306-6995, or mailed to:
Mail Stop Assignment Recordation Services, Director of the USPTO, P.O. Box 1450, Alexandria, V.A. 22313-1450

ASSIGNMENT

FOR VALUABLE CONSIDERATION, THE RECEIPT AND ADEQUACY OF WHICH IS
HEREBY ACKNOWLEDGED, I/WE OsteoTools, LLC, of 1 University
Plaza, Suite 405, Hackensack, N.J. 07601, hereby sell, assign,
and transfer unto BioDynamics, LLC, a corporation of New Jersey,
located at 84 Honeck Street, Englewood, N.J. 07631 the entire
right, title, and interest in and to my/our application for
Letters Patent of the United States filed on July 22, 2002 as
application Serial No.10/200,355, entitled:

BIOABSORBABLE PLUGS CONTAINING DRUGS

and my/our entire right, title, and interest in and to all my/our
inventions, whether joint or sole, disclosed in said application
for Letters Patent, and in and to all divisional or continuation
applications or continuation-in-part applications that may be
filed for United States Letters Patent for any of said
inventions, or any patent application inside or outside the
United States claiming benefit of priority of this application
and in and to all patents that may be granted on the foregoing
applications, and I/we hereby agree, whenever requested, to
communicate to said assignee, its successors and assigns, any
facts known to me/us respecting said inventions and to execute
all applications or papers necessary to obtain and maintain
proper patent protection on said inventions.

Date

4/1/05

Jane Grinch, Esq. for OsteoTools, LLC

State of

New Jersey

SS:

County of

Somerset

Before me personally appeared: Jane Grinch, Esq.
and acknowledged the foregoing instrument to be his/her free act and
deed this 1st day of April, 2005

Seal

Denise M. Markinson

DENISE M. MARKINSON
NOTARY PUBLIC OF NEW JERSEY
Commission Expires 11/19/2008



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application of:

JAMES D. RALPH, et al.

Serial No.: 10/200,355

Filed: July 22, 2002

For: BIOABSORBABLE PLUGS
CONTAINING DRUGS

Group Art Unit: 1615

Examiner: Sheikh, Humera N.

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Date of Deposit: May 18, 2005

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Print Name: Carolyn P. Stanton

Signature: Carolyn P. Stanton

LETTER TO OFFICIAL DRAFTSPERSON

Sir:

Enclosed herewith in connection with the patent application referenced above are two sheets of formal drawings for your consideration.

A Notice of Allowance and Fee(s) Due was mailed on March 8, 2005 having a date due of June 8, 2005. The Issue Fee was paid on April 6, 2005.

The application was filed with informal drawings but there does not appear to be any notice to that effect in the file. As soon as applicants discovered that formal drawings had not been filed they had the enclosed drawings prepared for submission to the Office.

The draftsperson is invited to telephone the undersigned at 908-722-0700 to discuss any questions about the drawings.

The Commissioner is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account No. 14-1263. A duplicate copy of this paper is enclosed.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Wm R Robinson", written over a horizontal line.

William R. Robinson
Registration No. 27,224

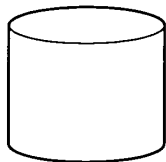
Date: May 18, 2005

Norris, McLaughlin & Marcus, P.A.
P.O. Box 1018
721 Route 202-206
Somerville, NJ 08876-1018
(908) 722-0700

104084-010



+



10a

FIG. 1A



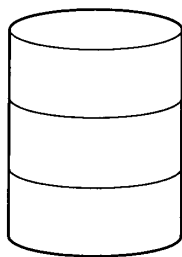
10b

FIG. 1B



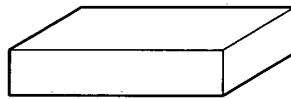
10c

FIG. 1C



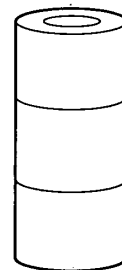
10d

FIG. 1D



10e

FIG. 1E



10f

FIG. 1F



10g

FIG. 1G



10h

FIG. 1H



10i

FIG. 1I



10j

FIG. 1J

+

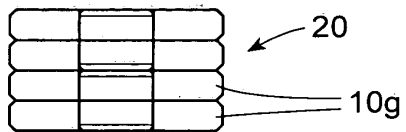


FIG. 2

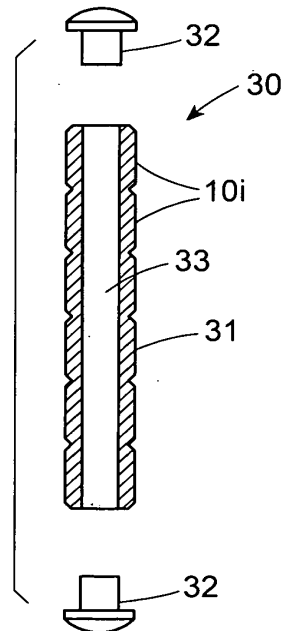


FIG. 3

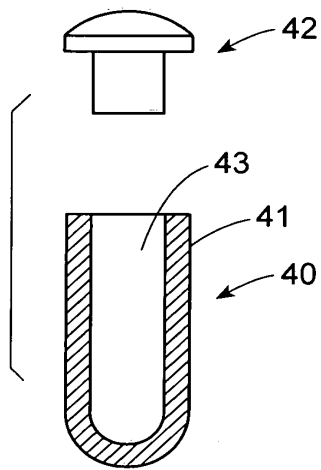


FIG. 4

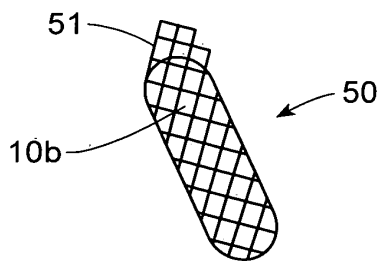


FIG. 5

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail

Mail Stop ISSUE FEE
 Commissioner for Patents
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 Alexandria, Virginia 22313-1450
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APR 06 2005

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

7590

03/08/2005

Nancy A. Bird
 231 Walton Avenue
 So. Orange, NJ 07079

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (703) 746-4000, on the date indicated below.

NANCY A. BIRD	(Depositor's name)
Nancy A. Bird	(Signature)
April 4, 2005	(Date)

04/07/2005 WABDEL3 00000070 10200355

01 FC:2501 700.00 OP
 02 FC:1504 300.00 OP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/200,355	07/22/2002	James Ralph	02RAL1	2385

TITLE OF INVENTION: BIOABSORBABLE PLUGS CONTAINING DRUGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	06/08/2005
EXAMINER	ART UNIT	CLASS-SUBCLASS			
SHEIKH, HUMERA N	1615	424-422000			

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

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

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

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

(A) NAME OF ASSIGNEE

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

BioDynamics, LLC

Englewood, New Jersey

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

4a. The following fee(s) are enclosed:

- ☒ Issue Fee
- ☒ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s):

- ☒ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature

Nancy A. Bird
 NANCY A. BIRD

Date

March 31, 2005
 28,398

Typed or printed name

Registration No.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

03/08/2005

Nancy A. Bird
231 Walton Avenue
So. Orange, NJ 07079

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/08/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/200,355	07/22/2002	James Ralph	02RAL1	2385

TITLE OF INVENTION: BIOABSORBABLE PLUGS CONTAINING DRUGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	06/08/2005

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

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

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

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
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Nancy A. Bird
231 Walton Avenue
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(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/200,355	07/22/2002	James Ralph	02RAL1	2385

TITLE OF INVENTION: BIOABSORBABLE PLUGS CONTAINING DRUGS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$700	\$300	\$1000	06/08/2005

EXAMINER	ART UNIT	CLASS-SUBCLASS
SHEIKH, HUMERA N	1615	424-422000

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

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, _____ 1
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. _____ 2
- _____ 3

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

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

(A) NAME OF ASSIGNEE

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

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

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

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- ☐ A check in the amount of the fee(s) is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

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- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

The Director of the USPTO is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/200,355	07/22/2002	James Ralph	02RAL1	2385
7590	03/08/2005			
Nancy A. Bird 231 Walton Avenue So. Orange, NJ 07079				
EXAMINER SHEIKH, HUMERA N				
ART UNIT PAPER NUMBER				
1615				

DATE MAILED: 03/08/2005

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

The Patent Term Adjustment to date is 378 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 378 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

ML

Notice of Allowability	Application No.	Applicant(s)	
	10/200,355	RALPH ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

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

1. ☒ This communication is responsive to 09 December 2004.
2. ☒ The allowed claim(s) is/are 1-20.
3. ☒ The drawings filed on 22 July 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

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

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

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

Attachment(s)

1. ☐ Notice of References Cited (PTO-892) 2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____ 4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. ☐ Notice of Informal Patent Application (PTO-152) 6. ☒ Interview Summary (PTO-413), Paper No./Mail Date <u>3/3/05</u> 7. ☒ Examiner's Amendment/Comment 8. ☒ Examiner's Statement of Reasons for Allowance 9. ☐ Other _____
--	--

THURMAN K. PAGE
 SUPERVISORY PATENT EXAMINER
 TECHNOLOGY CENTER 1600

DETAILED ACTION

Status of the Application

Receipt of the Amendment and Applicant's Arguments/Remarks, all filed 12/09/04 is acknowledged.

Claims 1-20 are pending. Claim 1 has been amended. New claims 10-20 have been added. Upon entry of the Examiner's Amendment, Claim 9 will have been amended, including amendments to the Specification.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Nancy A. Bird on March 03, 2005.

The application has been amended as follows:

In the Specification:

On page 1, line 5, the word '**agens**' has been changed to '**agents**'.

On page 7, line 18, the word '**agant**' has been changed to '**agent**'.

On page 13, line 4, after the word 'Dacron®' the phrase **“(manufactured by Invista North America S.A.R.I. Corporation), yarns of synthetic fibers, and synthetic fibers and filaments for use in the manufacture of fabrics and textiles,”** has been added.

On page 13, line 4, after the word 'Gortex®', the phrase **“(manufactured by W.L. Gore & Associates, Inc.), fabrics with polytetrafluoroethylene laminate”** has been added.

In the Claims:

In Claim 9, line 1, the word 'An' has been **replaced** with the word 'The'.

In Claim 9, line 1, after the word 'implantable', the words **“modular drug delivery”** have been **replaced** with the word **“prosthetic”**.

In Claim 9, line 1, after the word 'device', the words **“of claim 1”** have been added.

In Claim 14, line 2, the word 'paced' has been changed to 'placed'.

Allowable Subject Matter

Claims 1-20 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Wilcox *et al.* US 5,681,289 & Yi *et al.* US 6,656,488 B2) do not disclose nor fairly suggest an implantable prosthetic device having a surface contour and comprising a *solid* modular implantable drug delivery device that is

within a shaped recess within the outer surface of the implantable prosthesis. In contrast, the prior art's drug delivery device is located between a prosthesis and a bone. This results in the disturbance of the seating of the prosthesis itself and results in a loose fit of the implant. The prior art also fails to teach or suggest the release of therapeutic agents over a controlled release or predefined dosing period. The instant invention is seen as an improvement over prior art devices because the instant prosthetic device allows for surgical sites to remain closed once the therapeutic agents have been dispensed on the desired site, which is due to the placement of solid modules of therapeutic agent in the biodegradable polymer, thus avoiding septic or microbial infections. The prior art dispenses the chemical agent from holes in the bladder and not by biodegradation of the polymer. Applicants' invention uses solid modules of biodegradable polymer and a therapeutic agent, inserted into a recess in the prosthesis, to release the therapeutic agent during biodegradation of the polymer over a predefined dosing period, all of which is neither taught nor suggested by the prior art. In a personal interview, held on 11/18/04, with Applicants, Examiner and her supervisor, suggestions were made to amend claim recitations by incorporating the terms 'solid modular', 'prosthesis' and 'controlled release of the therapeutic agent over a predefined dosing period' to place the application in condition for allowance. Applicant has accepted and amended the claim language as suggested by the Examiner. Accordingly, the instant application is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

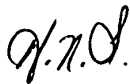
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

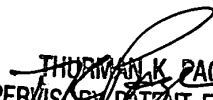
H. N. Sheikh



Patent Examiner

Art Unit 1615

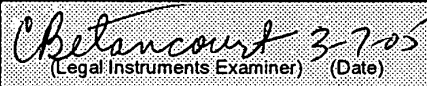
March 03, 2005



THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Substance of Interview including description of the general nature of what was discussed: Upon review of Applicant's amendment filed 12/09/04, the Examiner and her supervisor, T.K. Page proposed the following claim suggestions to place application in condition for allowance: (1) To amend Claim 9 by reciting 'The implantable prosthetic device of claim 1; and (2) To provide the generic source/definitions for the trademarks Dacron® and Gortex® listed on page 13 of the instant specification. Attorney accepted the proposed changes suggested by the Examiner and submitted the trademark information requested by the Examiner. The Examiner agreed to conduct an Examiner's Amendment making the necessary changes.

Issue Classification 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/200,355	RALPH ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

ISSUE CLASSIFICATION													
ORIGINAL					CROSS REFERENCE(S)								
CLASS		SUBCLASS			CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)							
424		422			424	426							
INTERNATIONAL CLASSIFICATION					623	23.75	23.76						
A	6	1	F	13/00									
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Humera N. Sheikh 3/3/05 (Assistant Examiner) (Date)					 HUMERA N. SHEIKH SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600 (Primary Examiner) (Date)								
 Chetan Court 3-7-05 (Legal Instruments Examiner) (Date)					Total Claims Allowed: 20 <table border="1"> <tr> <td>O.G. Print Claim(s)</td> <td>O.G. Print Fig.</td> </tr> <tr> <td>1</td> <td>1</td> </tr> </table>					O.G. Print Claim(s)	O.G. Print Fig.	1	1
O.G. Print Claim(s)	O.G. Print Fig.												
1	1												

☐ Claims renumbered in the same order as presented by applicant										☐ CPA					☐ T.D.					☐ R.1.47				
Final	Original			Final	Original			Final	Original			Final	Original			Final	Original							
1	1				31				61				121				151				181			
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	30				60				90				150				180				210			

Index of Claims 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/200,355		RALPH ET AL.	
	Examiner		Art Unit	
	Humera N. Sheikh		1615	

√	Rejected
=	Allowed

-	(Through numeral) Cancelled
+	Restricted

N	Non-Elected
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A	Appeal
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Claim		Date									
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Search Notes 	Application/Control No.		Applicant(s)/Patent under Reexamination	
	10/200,355		RALPH ET AL.	
	Examiner		Art Unit	
	Humera N. Sheikh		1615	

SEARCHED			
Class	Subclass	Date	Examiner
424	422	3/3/2005	HS
424	426	3/3/2005	HS
623	23.75	3/3/2005	HS
623	23.76	3/3/2005	HS

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner
424	422	3/3/2005	HS
424	426	3/3/2005	HS
623	23.75	3/3/2005	HS
623	23.76	3/3/2005	HS

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
WEST (US Pats, PG Pub, EPO, JPO, Derwent) * SPE Page determined allowability of claims after amendment	3/3/2005	HS



UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
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Bib Data Sheet

CONFIRMATION NO. 2385

SERIAL NUMBER 10/200,355	FILING OR 371(c) DATE 07/22/2002 RULE	CLASS 424	GROUP ART UNIT 1615	ATTORNEY DOCKET NO. 02RAL1	
APPLICANTS James Ralph, Seaside Park, NJ; Steve Tatar, Montville, NJ; ** CONTINUING DATA ** <i>None JS</i> ** FOREIGN APPLICATIONS ** <i>None JS</i> ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED.. SMALL ENTITY ** ** 08/20/2002					
Foreign Priority claimed ☐ yes ☒ no 35 USC 119 (a-d) conditions ☐ yes ☒ no ☐ Met met Allowance <i>JS</i> Verified and Acknowledged Examiner's Signature <i>JS</i> Initials		STATE OR COUNTRY NJ	SHEETS DRAWING 2	TOTAL CLAIMS 9	INDEPENDENT CLAIMS 2
ADDRESS Nancy A. Bird 231 Walton Avenue So. Orange, NJ 07079					
TITLE Bioabsorbable plugs containing drugs					
FILING FEE RECEIVED 370	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

Dec. 09 2004 03:45PM P1

RECEIVED
CENTRAL MAIL CENTER

Law Offices of Nancy A. Bird
231 Walton Avenue, So. Orange, N.J. 07079
E-mail: nancyalicebird@aol.com
Phone: (973)-761-0714
Fax: (973)-761-0535

DEC 09 2004

DATE: December 9, 2004
TO: United States Patent and Trademark Office
Technology Center 1600, Art Unit 1615
Examiner: Sheikh, Humera
RE: Application Serial No. 10/200,355
FAX NO.: (703) 872-9306
PHONE NO.: (571) 272-0604

FROM: Nancy A. Bird

RE DOCKET #: JR1

Total pages (including cover): 16
Transmittal Form (1 page)
Response (14 pages)

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PAGE 1/16 * RCVD AT 12/9/2004 2:27:12 PM [Eastern Standard Time] * SVR:USPTO-EFAXRF-1/0 * DNIS:8729306 * CSID:973 761 0535 * DURATION (mm-ss):07-10

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

RECEIVED
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DEC 09 2004

PTO/SB/21 (09-04)

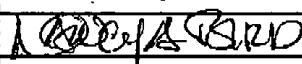
Approved for use through 07/31/2008. OMB 0851-0031

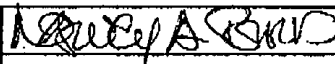
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/200,355
	Filing Date	07/22/2002
	First Named Inventor	RAph. James
	Art Unit	1615
	Examiner Name	Sheldh, Humera
	Attorney Docket Number	JR1
Total Number of Pages in This Submission	15	

ENCLOSURES (Check all that apply)		
☐ Fee Transmittal Form ☐ Fee Attached ☒ Amendment/Reply ☐ After Final ☐ Affidavits/declaration(s) ☐ Extension of Time Request ☐ Express Abandonment Request ☐ Information Disclosure Statement ☐ Certified Copy of Priority Document(s) ☐ Reply to Missing Parts/ Incomplete Application ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53	☐ Drawing(s) ☐ Licensing-related Papers ☐ Petition ☐ Petition to Convert to a Provisional Application ☐ Power of Attorney, Revocation Change of Correspondence Address ☐ Terminal Disclaimer ☐ Request for Refund ☐ CD, Number of CD(s) _____ ☐ Landscape Table on CD	☐ After Allowance Communication to TC ☐ Appeal Communication to Board of Appeals and Interferences ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ☐ Proprietary Information ☐ Status Letter ☐ Other Enclosure(s) (please identify below):
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm Name	Law Offices of Nancy A. Bird	
Signature		
Printed name	Nancy A. Bird	
Date	December 9, 2004	Reg. No. 28,398

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:		
Signature		
Typed or printed name	Nancy A. Bird	Date December 9, 2004

This collection of information is required by 37 CFR 1.5. 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 2 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. 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.

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

Dec 09 2004 03:46PM P3

CENTRAL INTELLIGENCE AGENCY

DEC 09 2004

Docket No. JR1

UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Application of : **James D. Ralph**
Appl. No. : **10/200,355**
Filed : **July 22, 2002**
For : **Bioabsorbable Plugs Containing Drugs**
Examiner: **SHEIKH, H. N.** Art Unit: 1615

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

December 9, 20004

AMENDMENT

Sir:

In response to the Office Action dated October 4, 2004, please amend the
above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2
of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior version, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) An implantable prosthetic device having a surface contour, and comprising a solid modular implantable drug delivery device adapted to be received within a shaped recess within an ~~the~~ outer surface of an implantable prosthesis wherein the outer surface of the prosthesis has a surface contour, said device being operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal, the device comprising:

(a) solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and

(b) a therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer over a predefined dosing period.

2. (Original): The device of claim 1 wherein when said solid module comprising a biodegradable polymer is received within the shaped recess of the implantable

prosthesis, the contour of the outer surface of the prosthesis is not substantially altered.

3. (Original): The device of claim 1 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.

4. (Original): The device of claim 2 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.

5.(Original): The device of claim 1 wherein said therapeutic agent is contained within-a cavity in said solid module.

6. (Original): The device of claim 2 wherein said therapeutic agent is contained within a cavity in said solid module.

7. (Original): The device of claim 1 comprising a plurality of solid modules.

8. (Original): The device of claim 7 wherein said plurality of solid modules are affixed to one another.

9. (Original): An implantable modular drug delivery device comprising: (a) a mesh container; and (b) at least one solid module comprising a biodegradable polymer and a therapeutic agent contained within, said mesh container.

10. (New:) The implantable prosthetic device of Claim 1 wherein the prosthesis is a

femoral pin.

11. (New): The implantable prosthetic device of Claim 1 wherein the prosthesis is a bone plate.

12. (New): The implantable prosthetic device of Claim 11, wherein the solid module is shaped like a rectangular tile, and the recess is a mating receptacle therefor.

13 (New): The implantable prosthetic device of Claim 1 wherein the recess is formed by drilling a hole in the prosthesis.

14. (New): The implantable prosthetic device of Claim 1, wherein the solid module is shaped like a rod, and is paced within a cylindrical recess in the prosthesis.

15. (New): The implantable prosthetic device of Claim 7, wherein one of the solid modules is hollowed out to increase the surface area in contact with the body fluids, and increase the rate of release of a therapeutic agent therefrom.

16. (New): The implantable prosthetic device of Claim 1, wherein the solid module is shaped like a tapered conical plug

17. (New): The implantable prosthetic device of Claim 1, wherein the solid module is shaped like a threaded cylindrical plug.

18. (New): The implantable prosthetic device of Claim 7, wherein the modules comprise

a plurality of stacked disks.

19. The implantable prosthetic device of Claim 1, wherein the solid module is shaped like a capped tub.

20. (New): A method for controlled phased release of a therapeutic agent into an orthopedic surgical site, comprising providing an implantable prosthesis, forming at least one shaped solid modular drug delivery device comprising a biodegradable polymer and a therapeutic agent, forming a recess in the surface of the prosthesis shaped to receive the shaped solid modular drug delivery device, placing at least one shaped solid modular drug delivery device in the recess, and implanting the prosthesis in the body of an animal.

REMARKS

Applicants would like to thank the Examiners for th interview granted on November 18, 2004, and the opportunity to discuss the scope of the prior art and the explain the details the present invention. Claim 1, and claims 2-8, dependant thereon, have been amended to recite, an "implantable prosthetic device", "solid modular" drug delivery devices, and the controllable release of the therapeutic agent "over a predefined dosing period", as indicated in the Interview Summary.

A. STATUS OF THE CLAIMS

Claims 1-9 are still pending. Claims 10-20 are added.

Claim 1 is amended herein to change the scope of the claim to an implantable prosthetic device with the solid modular drug delivery device in a recess thereof. Support for this amendment may be found, e.g., at page 1, line 1. Claim 1 has also been amended to include the phrase "over a predefined dosing period". Support for this amendment may be found at page 7, lines 14-15, of the present application.

Newly added Claims 10 and 11, describe the prosthetic device as a femoral pin and bone plate, respectively. Support for these claims may be found at page 8, line 3.

Newly added Claim 12, describes the prosthetic device as rectangular tile, and

the recess as a mating receptacle. Support for this claim may be found at page 11, lines 15-18.

Newly added Claim 13, describes drilling the recess in the prosthetic device.

Support for this claim may be found at page 8, lines 11-12.

Newly added Claim 14, describes a solid modular drug delivery device shaped like a rod, and placed in a cylindrical recess. Support for this claim may be found at page 10, lines 13-24.

Newly added Claim 15, describes a solid modular drug delivery device which has been hollowed out. Support for this claim may be found at page 12, lines 1-3.

Newly added Claim 16, describes a solid modular drug delivery device shaped like a tapered conical plug. Support for this claim may be found at page 8, line 10.

Newly added Claim 17, describes a solid modular drug delivery device which is shaped like a threaded cylindrical plug. Support for this claim may be found at page 8, lines 10-11.

Newly added Claim 18, describes a solid modular drug delivery device comprises a plurality of stacked disks. Support for this claim may be found at page 8, line 10.

Newly added Claim 19, describes a solid modular drug delivery device which is

shaped like a capped tube. Support for this claim may be found at page 12, lines 3-4.

Newly added Claim 20, describes a method for the controlled phased release of a therapeutic agent into an orthopedic surgical site. Support for this claim may be found at page 5, lines 2-4, and page 7, line 11 to page 9, line 1.

B. REJECTION OF CLAIMS 1- 8 UNDER 37 U.S.C.102(b)

In the above identified office action the Examiner has rejected Claims 1-8 under 35 USC 102 (b) as being anticipated by Wilcox et al. (U.S. Patent No. 5,681,289) which is cited as disclosing a chemical agent dispensing system consisting of a sump or bladder appropriately shaped to be implanted between a bone surface and a prosthesis fitted thereto, or immediately adjacent a broken bone or injured tissue area. The bladder in Wilcox may be formed from a thin flexible biocompatible material. The internal cavity of the bladder connects to an open tube through which a chemical agent is passed. Continuing, the Examiner states that the bladder of Wilcox may be shaped like a prosthetic implant such as a stem, acetabular component, distal femoral knee component, or tibial tray, formed to contain and dispense a chemical agent. Further, the Examiner cites Wilcox as disclosing a bladder which may be fit into the passageway or cavity of

intramedullary rod or nail, for insertion into a patient's intramedullary canal. Wilcox is also cited for disclosing a fixation device which may be pinned to a bone adjacent a bone fracture. Lastly, the Examiner refers to the description of the drawings, at columns 5 -14, as describing various bladder configurations, formed of biodegradable materials that are shaped to fit between a prosthesis or bone surface.

Applicant respectfully disagrees that Wilcox et al describes the invention of the present application. Applicant's drug delivery device is not located between a prosthesis and the bone, but within a recess in the prosthesis. Further, in the present invention the therapeutic agent is released by the biodegradation of the biocompatible polymer, not dispensed through preformed holes, 22, in the bladder, as in Wilcox

In addition, though the structure of Wilcox Permits the doctor to dispense a chemical agent to the surgical site, hours and days after the surgery has been completed, the means used to accomplish this present quite a risk to the patient. First, the indwelling tube presents an avenue of ingress for microbes on the skin surface. Second, oxygen traveling through the tube to the surgical site can support bacterial growth. Third, by placing the bladder between the bone and the prosthesis Wilcox et al disturbs the "seating" of the prosthesis itself. For these reasons the structure described in Wilcox Is

not a safe means to dispense a chemical agent to an orthopedic surgical site.

In utilizing applicant's invention, the surgical site is closed. Therapeutic agents to be dispensed on site, hours and days after closing the site, must be left in the site. This is accomplished by placing preformed solid modules of therapeutic agent in biodegradable polymer. These solid modules are placed in a recess in the prosthesis, or sewn into the site. The modules are formed, and selected by the surgeon, to release the therapeutic agent over a predefined dosing period. Hence, Applicant maintains that Claim 1, Claims 2-9, dependent thereon, and newly added Claims 10-x, are not anticipated by Wilcox

C. REJECTION OF CLAIMS 1-8 UNDER 37 U.S.C.103(a)

The Examiner has also rejected Claims 1-8 under 37 U.S.C.103(a) as being unpatentable over the Wilcox et al. (U.S. Patent No. 5,681 289) disclosure as stated above; characterizing the present invention as a modular drug delivery device comprising a biodegradable polymer dimension to fit within a prosthesis; and further stating that the prior art teaches "devices...shaped to be received and affixed between a prosthesis or a bone surface", rendering the instant invention *prima facie* obvious over Wilcox.

Applicants respectfully disagree.

As set forth above, the solid modules of the present invention are not dimensioned to fit within a prosthesis as disclosed by Wilcox. Applicants believe the placement of the bladder of Wilcox inside the knee or the intramedullary canal will interfere with the seating of the implant, and will result in a loose fit. As described in the specification, it is important to maintain the surface contour of the prosthesis. According to the present invention, the solid modules are placed within a recess of the surface contour of the prosthesis.

In addition, as stated above, Wilcox dispenses the chemical agent from holes in the bladder, not by biodegradation of the polymer as in the present invention. Further, to dispense chemical agents to the surgical site postoperatively, Wilcox utilizes a bladder placed adjacent the prosthesis, which will interfere with the seating and eventual fit of the prosthesis, and an open tube into the surgical site which can cause and accelerate on site infection. Applicants invention uses solid modules of biodegradable polymer and a therapeutic agent, inserted into a recess in the prosthesis, to release the therapeutic agent during biodegradation of the polymer over a predefined dosing period. Hence, Applicants maintains that Claims 1-8 are not rendered obvious by the Wilcox patent.

D. REJECTION OF CLAIM 9 UNDER 37 U.S.C.103(a)

In the Office Action the Examiner has rejected Claim 9 under 37 U.S.C.103(a) as being unpatentable over Wilcox , as applied to Claims 1-8 above, and further in view of Yi et al.(U. S. Patent No. 6,656,488, stating that though Wilcox fails to teach a mesh container, one of ordinary skill in the art would employ containers of any material, depending on the desired or intended purpose, as evident for Yi. Yi is sited as disclosing a device for tissue engineering comprising a bioabsorbable bag containing bioabsorbable materials, cells or wound healing stimulants and biodegradable enzymes. The bag being made of mesh-like structures and mesh products, preferably VICRYL® mesh. The bags may comprise other bioabsorbable material. Completing the rejection, the Examiner states that the combination of Wilcox And Yi Would have been obvious as Wilcox used an implantable device (bladder) comprising biodegradable material to deliver active agents, and Yi Uses a mesh bag comprising biodegradable materials and active agents. Applicants respectfully disagrees. The bladder of Wilcox is used to dispense a chemical agent. The bag of Yi is used to created a formable device which will be replaced by tissue ingrowth, in, hopefully, the same form, a much more complicated

device than the simple dispenser of Wilcox. To this end, the bag of Yi contains a binding gel is injected into the bag. Insertion of a binding gel into the mesh bag of Applicants's invention alter the predetermined dosing period established in the manufacture of the solid modules. Further, for the reasons stated above with regard to Claims 1-8, Wilcox does not describe, nor render obvious the solid modules of biodegradable polymer comprising a therapeutic agent that is released during biodegradation of the polymer over predefined dosing period. Hence, Applicants maintain that Claim 9 is not obvious from Wilcox in view of Yi.

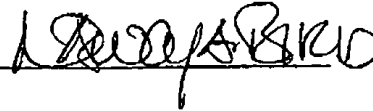
E. CONCLUSION

In view of the amendments made, and arguments presented, it is respectfully submitted that the present application is now in condition for allowance. If the Examiner has any questions, she may feel free to telephone the undersigned at (973) 761-0714.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

LAW OFFICES OF NANCY A. BIRD

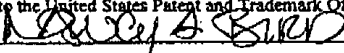
By: 

Nancy A. Bird
Reg. No. 28,398

Law Offices of Nancy A. Bird
231 Walton Ave.
So. Orange, NJ 07079

Certificate of Transmission under 37 CFR 1.8

I hereby certify that this correspondence is being facsimile transmitted
to the United States Patent and Trademark Office on December 9, 2004


Signature
NANCY A. BIRD

Typed or printed name of person signing Certificate

File name: 12-9-04 Amendment.wpd

PATENT APPLICATION FEE DETERMINATION RECORD

Effective January 1, 2003

Application or Docket Number

10/200,355

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS		
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	minus 20=	*
INDEPENDENT CLAIMS	minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

12/9/09

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 20	Minus ** 20	=
Independent	* 3	Minus *** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

52-08103

SMALL ENTITY

TYPE ☐

OR

OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	\$ 375
X\$ 9=	
X42=	
+140=	
TOTAL	

RATE	FEE
BASIC FEE	\$ 790
X\$18=	
X84=	
+280=	
TOTAL	

SMALL ENTITY

OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X44	
+140=	
TOTAL	
ADDITIONAL FEE	

RATE	ADDITIONAL FEE
X\$18=	
X88	
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TOTAL	
ADDITIONAL FEE	

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	
ADDITIONAL FEE	

RATE	ADDITIONAL FEE
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+280=	
TOTAL	
ADDITIONAL FEE	

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ADDITIONAL FEE	

RATE	ADDITIONAL FEE
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TOTAL	
ADDITIONAL FEE	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/200,355	07/22/2002	James Ralph	02RAL1	2385
7590 10/04/2004				
Nancy A. Bird 231 Walton Avenue So. Orange, NJ 07079			EXAMINER SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 10/04/2004

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

Office Action Summary	Application No. 10/200,355	Applicant(s) RALPH ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 14 October 2003.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-9 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) ☐ Notice of Informal Patent Application (PTO-152) 6) ☐ Other: _____.
--	--

DETAILED ACTION

Status of the Application

Receipt of the Power of Attorney Notice filed 10/14/03 is acknowledged.

Claims 1-9 are pending. Claims 1-9 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilcox *et al.* (US Pat. No. 5,681,289).

Wilcox *et al.* disclose a chemical agent dispensing system of a sump(s) or bladder(s) that are shaped appropriately to be implanted between a bone surface and a prosthesis fitted thereto, or immediately adjacent to a broken bone or injured tissue area. The system includes at least one bladder formed from a thin flexible biocompatible material, having an internal cavity that connects to an open tube wherethrough the chemical agent is passed. Wilcox *et al.* also disclose a sump or bladder having the shape of a prosthetic implant, such as a stem, acetabular component, distal femoral knee component, or tibial tray that itself is formed to contain and

dispense a chemical agent. Also disclosed by Wilcox *et al.*, is a sump or bladder that is arranged for fitting into to travel within and along a longitudinal passage or cavity an intramedullary rod or nail that is for insertion into a patient's intramedullary canal. A fixation device for pinning to sections of a bone adjacent to a bone fracture for delivering a chemical agent is also disclosed (see Abstract and column 1, line 65 – column 3, line 6).

The Figure drawing descriptions at columns 5-14, demonstrate various sump or bladder configurations, formed of biodegradable materials that are shaped to fit between a prosthesis or bone surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilcox *et al.* (US Pat. No. 5,681,289).

Wilcox *et al.*, as delineated above, teach a chemical agent dispensing system of a sump(s) or bladder(s) that are shaped appropriately to be implanted between a bone surface and a prosthesis fitted thereto, or immediately adjacent to a broken bone or injured tissue area. The system includes at least one bladder formed from a thin flexible biocompatible material, having an internal cavity that connects to an open tube wherethrough the chemical agent is passed. Wilcox *et al.* also disclose a sump or bladder having the shape of a prosthetic implant, such as a stem, acetabular component, distal femoral knee component, or tibial tray that itself is formed to contain and dispense a chemical agent. Also disclosed by Wilcox *et al.*, is a sump or bladder that is arranged for fitting into to travel within and along a longitudinal passage or cavity an intramedullary rod or nail that is for insertion into a patient's intramedullary canal. A fixation device for pinning to sections of a bone adjacent to a bone fracture for delivering a chemical agent is also disclosed (see Abstract and column 1, line 65 – column 3, line 6).

The Figure drawing descriptions at columns 5-14, demonstrate various sump or bladder configurations, formed of biodegradable materials that are shaped to fit between a prosthesis or bone surface.

The instant invention is drawn to a modular implantable drug delivery device comprising:
a) a biodegradable polymer dimensioned to fit within a prosthesis and b) a therapeutic agent that is released during biodegradation of the biodegradable polymer.

The prior art expressly teaches chemical agent dispensing devices comprising sumps or bladders containing biodegradable polymers (*i.e.*, silicone, polyurethanes, polylactic acids) and active ingredients (*i.e.*, antibiotics, anesthetics, degradative enzymes, etc), wherein the sumps or bladders are shaped to be received and affixed between a prosthesis or a bone surface. Hence, there is no significant distinction observed between the instant invention and the prior art, since the art generically and specifically teaches implantable devices for the treatment of injured sites and tissues. Thus, the instant invention is rendered *prima facie* obvious over the prior art of record.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilcox *et al.* (US Pat. No. 5,681,289) as applied to Claims 1-8 above and further in view of Yi *et al.* (US Pat. No. 6,656,488 B2).

The teachings of Wilcox *et al.* have been discussed above. Wilcox *et al.* are deficient only in the sense that they do not teach a mesh container. It is deemed obvious to one of ordinary skill in this art to employ devices with containers comprised of any material, depending on the desired or intended purpose. Such skill is also evident from the reference of Yi *et al.* ('488).

Yi *et al.* ('488) teach a device for tissue engineering comprising a bioabsorbable bag containing bioabsorbable materials, cells or wound-healing stimulants and biodegrading enzymes, whereby the bioabsorbable bag is made of mesh-like structures and mesh products. A

preferred mesh product is VICRYL® mesh. The bioabsorbable bags may comprise any biocompatible material including polylactic acid (PLA), polyglycolic acid (PGA), polycaprolactone (PCL) and the like. The device can be used to promote in-growth of host tissue into a void by inserting the bag with its contents into the void and conforming the bag to a desired shape (see reference column 3, lines 30-60) and Abstract.

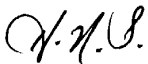
It would have been obvious to one of ordinary skill in the art at the time of the invention to use the combined teachings of Yi *et al.* within Wilcox *et al.* because Yi *et al.* teach a mesh bag container comprising biodegradable materials (*i.e.*, polylactic acid) and active agents (*i.e.*, wound-healing agents; biodegradative enzymes) and similarly, Wilcox *et al.* teach an implantable device comprising biodegradable materials (*i.e.*, polylactic acid) to deliver active ingredients, such as degradative enzymes. The expected result would be a contained, implantable drug delivery device for the treatment of injured tissues and sites.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

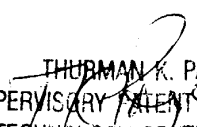
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

H. N. Sheikh 

Patent Examiner

Art Unit 1615

September 22, 2004


THURMAN R. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited	Application/Control No. 10/200,355	Applicant(s)/Patent Under Reexamination RALPH ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,681,289	10-1997	Wilcox et al.	-- --
*	B	US-6,656,488	12-2003	Yi et al.	-- --
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

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

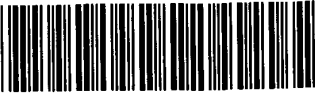
Index of Claims 		Application No. 10/200,355 Examiner Humera N. Sheikh		Applicant(s) RALPH ET AL. Art Unit 1615	
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√	Rejected	–	(Through numeral) Cancelled	N	Non-Elected	A	Appeal
=	Allowed	+	Restricted	I	Interference	O	Objected

Claim		Date			
Final	Original	9/22/04			
	1	√			
	2	√			
	3	√			
	4	√			
	5	√			
	6	√			
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	148				
	149				
	150				

Search Notes 	Application No.	Applicant(s)	
	10/200,355	RALPH ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

SEARCHED			
Class	Subclass	Date	Examiner
424	422	9/22/2004	HS
424	426	9/22/2004	HS
623	23.75	9/22/2004	HS
623	23.76	9/22/2004	HS

INTERFERENCE SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES (INCLUDING SEARCH STRATEGY)		
	DATE	EXMR
WEST (US Pats, PG Pub, EPO, JPO, Derwent)	9/22/2004	HS

WEST Search History

Hide Items Restore Clear Cancel

DATE: Wednesday, September 22, 2004

Hide?	Set Name	Query	Hit Count
	DB=PGPB,USPT,USOC,EPAB,JPAB,DWPI,TDBD; PLUR=YES; OP=OR		
☐	L11	L10 and (prosthetic or prosthesis)	40
☐	L10	mesh adj5 (bag or container)	5338
☐	L9	(implant or prosthetic) same (mesh adj5 container or container adj8 mesh)	5
☐	L8	implant and (mesh adj5 container or container adj8 mesh)	48
☐	L7	implant and mesh adj5 container	27
☐	L6	L3 and biodegradable adj9 polymer	131
☐	L5	L4 and device	488
☐	L4	L3 and polymer	556
☐	L3	L2 and (prosthetic or prosthesis)	927
☐	L2	implant same (mesh adj8 container or mesh)	1863
☐	L1	implant and (mesh adj8 container or mesh)	8972

END OF SEARCH HISTORY

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P.O. Box 1450
ALEXANDRIA, VA 22313-1450
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JUN - 3 2004

NANCY A. BIRD
231 WALTON AVENUE
SO. ORANGE NJ 07079

In re Application of
James Ralph et al
Serial No.: 10/200,355
Filed: February 25, 2003
Attorney Docket No.: JR1

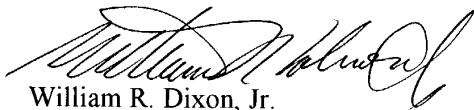
:
:
: PETITION TO MAKE SPECIAL
:
:

This is in response to applicants' petition filed May 10, 2004, to make the above-identified application special under the provisions of 37 CFR 1.102(c), based on the age of the applicant.

Applicant has not satisfied the provisions set forth in M.P.E.P. 708.02, IV. No evidence or verified statement of one or more applicant's being over 65 years of age has been provided. Therefor the petition is **DISMISSED**. Reconsideration of this decision may be had by providing the required evidence or statement.

The application will be acted on in turn.

Should there be any questions with regard to this letter please contact William R. Dixon, Jr. by letter addressed to the Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at 571-272-0519 or by facsimile transmission to the general Office facsimile number.



William R. Dixon, Jr.
Special Program Examiner
Technology Center 1600



1615

PETITION TO THE COMMISSIONER
TO ADVANCE EXAMINATION
UNDER 37 CFR 1.102
Docket No. JR1

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner: **Sheikh, Humera N.** Art Unit: 1615
Re: Application of: **Ralph, James**
Serial No.: 10/200,355
Filed: July 22, 2002
For: **Bioabsorbable Plugs Containing Drugs**

PETITION TO ADVANCE EXAMINATION UNDER 37 CFR 1.102

Mail Stop Petition
Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Va 22313-1450

May 3, 2004

Sir:

I hereby petition the Commissioner of Patents to Advance the Examination of the above-identified Application. Applicants request the Commissioner grant this petition, to make this application special, based on the age of co-inventor Steve Tatar, aged 76.

There is no fee due under this petition, according to 37 C.F.R. 1.102(c)

I am the attorney of record, Registration No. 28, 398.

Respectfully Submitted,

Nancy A. Bird
Registration No. 28, 398

Law Offices of Nancy A. Bird
231 Walton Avenue
So. Orange, N.J. 07079

TEL: (973) 761-0714
FAX: (973) 761-0535



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/200,355	07/22/2002	James Ralph	02RAL1

Nancy A. Bird
 231 Walton Avenue
 So. Orange, NJ 07079

CONFIRMATION NO. 2385



OC000000011058230

Date Mailed: 10/17/2003

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 10/14/2003.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Coralia Betancourt

CORALIA BETANCOURT
 1600 (703) 308-3570

OFFICE COPY

FROM : NANCY A. BIRD, ESQ.
05/21/03 14:38 FAX

PHONE NO. : 973 761 0535

Oct. 14 2003 02:27PM P2

001

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

May. 12 2003 12:30 PM

4/ Power of
Atty

Under the Trademark Reduction Act of 1990, no person may prepare or submit to a collection of information unless it contains a valid and current power of attorney.

Approved for use through 11/30/2003 OMB 0591-0008
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	Application Number: 10/200,355
	Filing Date: 07/22/2002
	First Name/Inventor: James Ralph
	Title: Researchable plus containing drug
	App Link: 1616
	Examiner Name: N/A
	Attorney Contact Number: 181

I hereby appoint:

☒ Practitioner of Customer Number: 34197 → Place Customer Number Bar Code Label here

OR

☐ Practitioner named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transmit all messages in the United States Patent and Trademark Office consistent therewith.

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☐ Firm or Individual Name:

Address	
Address	
City	
State	
Zip	
Country	
Telephone	
Fax	

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.72(n) is enclosed. (Form PTO/A-850)

SIGNATURE OF APPLICANT OR ASSIGNEE OF RECORD

Name: James Ralph	
Signature: <i>James Ralph</i>	
Date: May 12, 2003	Telephone: (610) 315-0254

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representatives are required. Submit copies of the signatures of all the inventors or assignees of record of the entire interest or their representatives if more than one signature is required. See below.

☐ Total of _____ forms are submitted.

This submission of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public action is to the form by the USPTO to process an application. Confidentiality is provided by 35 U.S.C. 122 and 37 CFR 1.34. This submission is submitted to the USPTO. Time will vary depending upon the individual case. Any responses on the drawing of time you require to complete the form, please request for extension of time. The information should be sent to the Office of Information Systems, U.S. Department of Commerce, P.O. Box 1480, Alexandria, VA 22304-1480. DO NOT SEND PAGES OR COMPLETION FORMS TO THIS ADDRESS. Send the Completion Form for Patent, P.O. Box 1480, Alexandria, VA 22304-1480.

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Sent By: HP LaserJet 3100;

PHONE NO. : 973 761 0535
2014892992;

Oct. 14 2003 02:27PM P3
Page 1/1

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

Sep. 15 2003 09:30AM P4

PTO/SB/01 (05-03)
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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT	
Application Number	10/200,355
Filing Date	07/22/2002
First Named Inventor	James Ralph
Title	Bioabsorbable plugs containing drugs
Art Unit	1614
Examiner Name	N/A
Attorney Docket Number	NR1

I hereby appoint:

☐ Practitioner of Customer Number [] → Place Customer Number Bar Code Label Here

OR

☒ Practitioner(s) named below:

Name	Registration Number
Nancy A. Bird	28,398

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

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OR

☐ Practitioner of Customer Number: [] → Place Customer Number Bar Code Label Here

OR

☒ Form of Individual Name

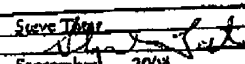
Law Office of Nancy A. Bird			
Address			
231 Walton Avenue			
Address		State	Zip
South Orange		New Jersey	07079
City		USA	
Country		Telephone	Fax
(973) 761-0714		(973) 761-0535	

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/98)

SIGNATURE of Applicant or Assignee of Record

Name	Steve Tatar		
Signature			
Date	September 2003	Telephone	

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representatives are required. Submit multiple forms if more than one signature is required. See below.

☐ Total of [] forms are submitted.

The collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public action is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 422 and 37 CFR 1.14. This collection is exempted to the maximum extent. Any comments including gathering, preparing, and submitting the completed application form to the USPTO. There are many depending upon the individual case. Any comments on the accuracy of time you require to complete the 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 1480, Alexandria, VA 22313-1480. DO NOT SEND P228 OR COMPLETED FORMS TO THIS ADDRESS. Send to: Communication for Patents, P.O. Box 1480, Alexandria, VA 22313-1480.

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Ex. 1005, p. 76

Intersect ENT, Inc. v. New Amsterdam, LLC, IPR2024-00713

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

Oct. 14 2003 02:26PM P1

✓

Law Offices of Nancy A. Bird
231 Walton Avenue, So. Orange, N.J. 07079
E-mail: nancyalicebird@aol.com
Phone: (973)-761-0714
Fax: (973)-761-0535

DATE: October 14, 2003
TO: United States Patent and Trademark Office
Technology Center 1600, Art Unit 1614
RE: Submission of new **Power of Attorney**, for
U. S. Serial No. 10/200,355
FAX NO.: (703) 308-4242
PHONE NO.: (703)- 308-1234

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FROM: Nancy A. Bird

pages (including cover): 3

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/200,355	07/22/2002	James Ralph	02RAL1

Michael G. Petit
 P. O. Box 91929
 Santa Barbara, CA 93190-1929

CONFIRMATION NO. 2385



OC000000010535948

#3

Date Mailed: 07/22/2003

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the Power of Attorney filed 05/22/2003. The Power of Attorney in this application is not accepted for the reason(s) listed below:

- The signature(s) of Steve Tatar, a co-inventor in this application, has been omitted. The Power of Attorney will be entered upon receipt of confirmation signed by said co-inventor.

CORALIA BETANCOURT
 1600 (703) 308-3570

OFFICE COPY

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

May. 12 2023, 12:30 PM PST

#2

[illegible]

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FROM : NANCY A. BIRD, ESQ.
03/21/03 14:00 FAX

PHONE NO. : 973 761 0535

May. 22 2003 11:24AM P2
001

FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

May. 12 2003 12:30PM P2

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POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	10/200,355
Filing Date	07/22/2002
First Name of Inventor	James Ralph
Title	Biodegradable plug containing drug
Art Unit	1614
Examiner name	N/A
Attorney Contact Number	IR1

I hereby appoint:

☒ Practitioner at Customer Number: 34197 → Place Customer Number Bar Code Label Here

OR

☐ Practitioner(s) named below:

Name	Registration Number

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

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Address: _____

City: _____ State: _____ Zip: _____

Country: _____

Telephone: _____ Fax: _____

I am the:

☒ Applicant/Inventor.

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/04)

SIGNATURE of Applicant or Assignee of Record

Name: James Ralph

Signature: _____

Date: May 12, 2003 Telephone: (610) 917-0254

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representatives are required. Submit multiple forms if more than one signature is required. See below.

☐ Total of _____ forms are submitted.

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FROM : NANCY A. BIRD, ESQ.

PHONE NO. : 973 761 0535

May. 22 2003 11:24AM P1

Law Offices of Nancy A. Bird
231 Walton Avenue, So. Orange, NJ, 07079
E-mail: nancyalicebird@aol.com
Phone: (973)-761-0714
Fax: (973)-761-0535

FAX RECEIVED

MAY 23 2003

GROUP 1600

DATE: May 22, 2003

TO: United States Patent and Trademark Office
Technology Center 1600, Art Unit 1614

RE: Submission of **Revocation of Power of Attorney**, and
new **Power of Attorney**, for
U. S. Serial No. 10/200,355

OFFICIAL

FAX NO.: (703) 308-4242

PHONE NO.: (703)- 308-1234

FROM: Nancy A. Bird

pages (including cover): 3

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Ex. 1005, p. 81

Intersect ENT, Inc. v. New Amsterdam, LLC, IPR2024-00713

7-24-02 10200395 02202

PATENT APPLICATION TRANSMITTAL LETTER
(Small Entity)

Docket No.
02RAL1

TO THE ASSISTANT COMMISSIONER FOR PATENTS

Transmitted herewith for filing under 35 U.S.C. 111 and 37 C.F.R. 1.53 is the patent application of:

James Ralph and Steve Tatar

For: **Bioabsorbable Plugs Containing Drugs**

Enclosed are:

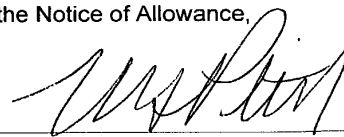
- ☒ Certificate of Mailing with Express Mail Mailing Label No. **EV118367040US**
☒ 2 sheets of drawings.
☐ A certified copy of a _____ application.
☒ Declaration ☒ Signed. ☐ Unsigned.
☒ Power of Attorney
☐ Information Disclosure Statement
☐ Preliminary Amendment
☐ _____ Verified Statement(s) to Establish Small Entity Status Under 37 C.F.R. 1.9 and 1.27.
☒ Other: **Stamped, Self-Addressed Postcard**

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	9	- 20 =	0	x \$9.00	\$0.00
Indep. Claims	2	- 3 =	0	x \$39.00	\$0.00
Multiple Dependent Claims (check if applicable) ☐					\$0.00
BASIC FEE					\$370.00
TOTAL FILING FEE					\$370.00

- ☒ A check in the amount of **\$370.00** to cover the filing fee is enclosed.
☐ The Commissioner is hereby authorized to charge and credit Deposit Account No. _____ as described below. A duplicate copy of this sheet is enclosed.
☐ Charge the amount of _____ as filing fee.
☐ Credit any overpayment.
☐ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: **July 22, 2002**



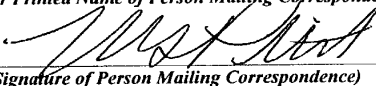
Signature

Michael G. Petit, Reg. No. 30,795

CC: **James Ralph**

P01SMALL/REV06

U.S. DEPARTMENT OF COMMERCE
NATIONAL BUREAU OF PATENT AND TRADEMARKS

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)			Docket No. 02RAL1
Applicant(s): James Ralph and Steve Tatar			
Serial No. Not Available	Filing Date Concurrent Herewith	Examiner Not Available	Group Art Unit Not Available
Invention: Bioabsorbable Plugs Containing Drugs			
I hereby certify that this <u>Original, nonprovisional utility patent application</u> (Identify type of correspondence) is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231-0001 on <u>July 22, 2002</u> (Date) <u>Michael G. Petit</u> (Typed or Printed Name of Person Mailing Correspondence) <u></u> (Signature of Person Mailing Correspondence) <u>EV118367040US</u> ("Express Mail" Mailing Label Number)			
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TITLE: Bioabsorbable Plugs Containing Drugs
INVENTORS: James Ralph and Steve Tatar
Docket No.: 02 RAL1

1 **BACKGROUND OF THE INVENTION**

2 1. Field of the Invention

3 The invention relates to methods and implantable devices for dispensing one or
4 more therapeutic agents at a surgical site. More particularly, the invention relates to
5 devices and methods for controllably delivering therapeutic agents to an orthopaedic
6 surgical site that requires the implantation of a prosthesis within the site.

7 2. Prior Art

8 Biodegradable materials are used in medicine for a variety of purposes including
9 drug delivery devices and as aids in tissue repair. The physical and chemical properties of
10 such materials can vary as in the case of different polymeric materials, e.g., melting point,
11 degradation rate, stiffness, etc. The variability in physical and chemical properties of
12 biodegradable polymeric materials allows biodegradable implants made from such
13 materials to be tailored to suit specific applications.

14 A resorbable bone wax is described in U.S. Pat. No. 5,143,730. The bone wax is
15 asserted to be suitable for mechanical staunching of bleeding and is based on oligomers
16 of glycolic acid and/or lactic acid with monofunctional and/or polyfunctional alcohols
17 and/or corresponding carboxylic acids.

18 U.S. Pat. Nos. 4,535,485 and 4,536,158 disclose certain implantable porous
19 prostheses for use as bone or other hard tissue replacement which are comprised of
20 polymeric materials. The disclosed prostheses are composed generally of polymeric
21 particles. The particles have an inner core comprised of a first biologically-compatible

1 polymeric material such as polymethylmethacrylate and an outer coating comprised of a
 2 second biologically-compatible polymeric material which is hydrophilic, such as
 3 polymeric hydroxyethylmethacrylate. The particles may incorporate a radiopaque
 4 material to render the particle visible in an X-ray radiograph. The particles may be
 5 bonded together to form a unitary structure which can be implanted in the body.
 6 Alternatively, a mass of the particles may be implanted in the body in an unbonded,
 7 granular form. In either the bonded or the unbonded form, interstices between the
 8 implanted particles form pores into which tissue can grow. Thus, the bioabsorbable
 9 particles serve as a structural support and guiding matrix for encroaching bone deposits
 10 derived from adjacent fresh bone. The hydrophilic coating on the particles facilitates
 11 infusion of body fluids into the pores of the implant, which promotes the ingrowth of
 12 tissue into the pores of the implant.

13 Chesterfield et al., in U.S. Patent 5,697,976, disclose a porous bioabsorbable
 14 surgical implant material that is prepared by coating particles of bioabsorbable polymer
 15 with tissue ingrowth promoter. Typical bioabsorbable polymers include polymers of
 16 glycolide, lactide, caprolactone, trimethylene carbonate, dioxanone, and physical and
 17 chemical combinations thereof. The tissue ingrowth promoter can include calcium
 18 hydroxide and/or a hydrophilic coating material. The hydrophilic coating material can be
 19 bioabsorbable or non-bioabsorbable. A typical non-bioabsorbable hydrophilic coating
 20 material is polyhydroxyethyl methacrylate (PHEMA). The bioabsorbable implant

1 material may also contain a therapeutic agent. Typical therapeutic agents include an
2 antimicrobial agent, dye, growth factors and combinations thereof.

3 Medical putty for tissue augmentation is described in U.S. Pat. No. 4,595,713 and
4 is alleged by the inventor to be useful in the regeneration of soft and hard connective
5 tissue. As described therein, the implant material is composed of a copolymer of 60-95%
6 epsilon caprolactone and 40-5% lactide. Catalysts used for the copolymer are metallic
7 esters of carboxylic acids. The polymer is said to become moldable at hot water
8 temperatures of about 115-160 °F.

9 Rosenthal et al., in U.S. Patent 5,700,476, disclose implant materials comprising a
10 matrix structure of sponge, at least one substructure and at least one pharmacologically
11 active agent, wherein both the matrix structure and the substructure are formed from
12 bioabsorbable biopolymers. The substructure may, for example, comprise biopolymer
13 films, flakes, fibres or microspheres embedded in the matrix structure of sponge. The
14 pharmacologically active agent may comprise antiseptics, antibiotics and/or analgesics.
15 One or more such therapeutically active agents may be incorporated separately into the
16 matrix and/or the substructure so as to achieve controlled or phasic release of the active
17 agents into the wound.

18 Great Britain Patent GB-A-2215209 describes a biodegradable, osteogenic bone-
19 graft substitute comprising: (a) a porous, rigid structure formed from a biodegradable
20 polymer such as polylactic or polyglycolic acid; (b) a chemotactic substance such as
21 hyaluronic acid, fibronectin or collagen dispersed in the interstices of the rigid structure;

1 and (c) a biologically active or therapeutic substance such as bone morphogenic protein
2 evenly distributed throughout the volume of the bone-graft substitute. In use, the material
3 is implanted into a bone defect. The material helps to restore functional architecture and
4 mechanical integrity of the bone, initiate osteogenesis, and maintain the biological
5 processes of bone growth while simultaneously being slowly bioabsorbed by the host
6 organism.

7 Akalla et al., in U.S. Patent 5,641,502, disclose a moldable biodegradable surgical
8 material made of a bioabsorbable polymer derived from hydroxyacids, lactones,
9 carbonates, etheresters, anhydrides, orthoesters and copolymers, terpolymers and/or
10 blends thereof. The polymer is blended with at least one surface active agent selected
11 from the group consisting of fatty acid ester and poly(oxypropylene)/poly(oxyethylene)
12 block copolymer. In one embodiment, a leaching agent is blended with the above-
13 mentioned surgical material. Methods of making moldable biodegradable surgical
14 material are provided. The surgical material may be used as a moldable bone wax in
15 connection with repair of wounds and is an adaptable aid for any appropriate surgical use,
16 e.g., hemostat, anchor, patch etc.

17 The porous bioabsorbable implants that have been suggested to date are generally
18 isotropic materials. That is to say, the structure and composition of the materials are
19 uniform in all directions. Any pharmacological therapeutic agents are generally
20 distributed uniformly in the biodegradable carrier materials. This, in turn, means that the
21 active agents are released uniformly into the wound site at a rate determined only by the

1 rate at which the implant material biodegrades and the surface area of the implant. In
2 practice, it would be preferable to have controlled or phased release of active agents. For
3 example, it may be desired to provide an implant having an initial rapid release of the
4 active therapeutic agent(s) to establish a sufficient concentration of those agents at the
5 wound surface, followed by the slower release required to maintain a constant
6 therapeutically effective concentration. Alternatively, it may be desirable to have an
7 initial rapid release of antiseptic followed by slower release of wound healing factors
8 such as cytokines, EGF etc.

9 In open surgical procedures, it is common to apply an antibiotic, analgesic,
10 growth stimulator, or other chemical agent at the surgical site prior to closing the incision
11 in order to control infection, decrease pain, promote growth, etc. One of the most
12 devastating complications of orthopaedic surgery such as total joint arthroplasty is deep
13 sepsis. Treatment of an infected joint replacement is difficult due to its location, and
14 localized devascularization resulting from this procedure. Current approaches to therapy
15 for deep infections include systemic or parenteral antibiotic regimes, and the use of
16 antibiotic-impregnated acrylic bone cement. Due to the localized devascularization, it is
17 difficult to establish therapeutic levels of an agent in the bone surrounding the implant
18 without exceeding toxic serum concentrations when utilizing systemic or parenteral
19 treatments. The use of antibiotic-containing bone cement results in high local
20 concentrations, while avoiding toxic serum levels, but the antibiotic has been shown to
21 elute in trace quantities for extended periods of time (greater than one year). Residual

1 trace amounts of antibiotics have raised concerns of resistant strain formation. An
2 additional concern regarding adding antibiotics to bone cement is the possible
3 degradation of mechanical properties of the bone cement whose primary function is as a
4 fixation material.

5 According to the state of the art, it is preferable to establish and maintain
6 therapeutic concentrations of an antibiotic at a surgical site for a period of 7 to 10 days,
7 with no residual antibiotics lingering for extended periods of time. It is also desirable to
8 achieve such relatively high therapeutic concentrations locally without elevating serum
9 concentrations, thereby reducing the danger of systemic toxicity.

10 U.S. Pat. No. 5,681,289 to Wilcox et al. discloses a dispensing bladder for passing
11 a low volume flow of a liquid chemical agent at an orthopaedic surgical site. The bladder
12 is installed adjacent to or as part of an orthopaedic implant. It is coupled to a tube which
13 receives a supply of liquid chemical such as an antibiotic via an injection port or an
14 implanted or external reservoir and pump. The bladder may be biodegradable so as to
15 avoid the need for extensive surgery to explant it. However, the tube, injection site,
16 pump, and reservoir must be surgically removed. Moreover, it is believed that the
17 delivery of a liquid antibiotic in the femoral canal may degrade the mechanical properties
18 of bone cement on an implant stem.

19 In view of the limitations of prior art implantable drug delivery devices, it is
20 desirable to provide an implantable drug delivery device in the form of a shaped plug that

1 may be affixed to a prosthesis, thereafter to biodegrade and deliver one or more
2 therapeutic agents contained therein at a controllable rate to the surrounding tissue.

3

4

SUMMARY

5 It is therefore an object of the invention to provide a modular drug delivery device
6 and method for controllably delivering a therapeutic agent to a surgical site, particularly
7 an orthopaedic surgical site into which a prosthesis has been implanted.

8 It is a further object of the invention to provide a device and a method for
9 attaching the device to an implantable prosthesis, the device thereafter being operable for
10 delivering an antibiotic to an orthopaedic surgical site and wherein the device does not
11 require surgical removal following implantation.

12 It is yet a further object of the invention to provide a drug delivery device meeting
13 the above objectives of delivering a therapeutic agent to an orthopaedic surgical site
14 which will deliver a therapeutic dose of the therapeutic agent to the surgical site over a
15 predefined dosing period.

16 In accordance with these objectives which will be discussed in detail below, the
17 bioabsorbable drug delivery devices in accordance with the various embodiments of the
18 present invention include encapsulating the therapeutic agent in a bioabsorbable polymer,
19 or a modular plug containing more than one bioabsorbable polymer, which will yield a
20 controllable release of the therapeutic agent over a predefined dosing period (such as a 7-
21 10 day period), with residual therapeutic agent being thereafter delivered only until the

1 bioabsorbable polymer is completely biodegraded. It is preferable that the drug delivery
 2 device be in the form of a rigid, preshaped polymeric plug that can be readily affixed to
 3 an orthopaedic prosthesis such as a femoral pin or a bone plate. Suitable therapeutic
 4 agents include antibiotics, analgesics and lactoferrin, and a suitable bioabsorbable
 5 polymer is poly lactide-co-glycolide (PLGA). Those skilled in the art will readily
 6 appreciate that other bioabsorbable polymers can be substituted for PLGA, for example
 7 (without limitation), PLA, etc.

8 Embodiments of a drug delivery device in accordance with the present invention
 9 include modular plugs configured as cylinders, capsules, disks, cylinders comprised of a
 10 plurality of stacked disks, a rectangular plaque or tile, a tapered conical plug or a threaded
 11 cylindrical plug that may be screwed into a hole drilled within a bone or the rigid body of
 12 a prosthesis or disposed within a mesh bag for implantation at a surgical site.

13 The features of the invention believed to be novel are set forth with particularity
 14 in the appended claims. However the invention itself, both as to organization and method
 15 of operation, together with further objects and advantages thereof may be best understood
 16 by reference to the following description taken in conjunction with the accompanying
 17 drawings in which:

18

19 **BRIEF DESCRIPTION OF THE DRAWINGS**

20 Figures 1a-j illustrate various embodiments of bioabsorbable drug delivery plugs
 21 in accordance with different configurations of the present invention.

1 Figure 2 is a cross-sectional view of an embodiment of a drug delivery device in
2 accordance with the present invention comprising a plurality of stacked annular modules
3 affixed to one another.

4 Figure 3 is a cross-sectional view of an implantable drug delivery device in
5 accordance with yet a further embodiment of the present invention comprising a plurality
6 of stacked tubular modules affixed to one another end-to-end.

7 Figure 4 is a longitudinal cross-sectional view of an implantable drug delivery
8 device comprising a sealable capsule in accordance with another embodiment of the
9 present invention.

10 Figure 5 is a perspective view of a capsular drug delivery module disposed within
11 an implantable mesh bag.

13 **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

14 It will be understood by the artisan that the bioabsorbable drug delivery devices
15 discussed hereinbelow may be formed out of polymer blends of glycolide and/or lactide
16 homopolymer, copolymer and/or glycolide/lactide copolymer and polycaprolactone
17 copolymers, and/or copolymers of glycolide, lactide, poly (L-lactide-co-DL-lactide),
18 caprolactone, polyorthoesters, polydioxanone, trimethylene carbonate and/or
19 polyethylene oxide or any other bioabsorbable material. Similarly, it will be further
20 understood that therapeutic agents suitable for timed release by the various embodiments
21 of the drug delivery device described herein include antibiotic compositions, analgesics,

1 lactoferrin and any other compositions effective for reducing infection and/or promoting
2 healing of a wound formed at a surgical site.

As used herein, the term "biodegradable" means that the composition will degrade over time by enzymatic action, by hydrolytic action and/or by other similar mechanisms in the human body. The term "bioabsorbable," means that the composition will be biodegraded and that the products of biodegradation will either be absorbed by tissue within the body or excreted.

Turning now to Figures 1a-j, various implantable modular drug delivery devices (herein after referred to alternatively as “implants” or “devices”) in accordance with the present invention are shown in perspective view. All embodiments of the device are designed to fit snugly within a receiving cavity in a prosthesis so as not to alter the profile thereof. Different embodiments 10a-10k of the device can be stacked and adhered together to generate new embodiments. Figure 1a shows a cylindrical implant 10a comprising a solid cylinder of a biodegradable polymer containing a therapeutic agent distributed substantially homogeneously throughout the volume thereof. The cylindrical device 10a may have a threaded exterior surface and a slotted head, as shown in Figure 1j, to enable the device 10a to be screwed into a hole tapped in a prosthesis (not shown).

Figure 1b is a perspective view of a capsular embodiment 10b of the device. The capsular embodiment 10b may be solid or have a hollow interior chamber. Either the interior chamber and/or the biodegradable polymer comprising the capsular material may include a therapeutic agent. Figure 1c shows a disk embodiment 10c of the device. The

1 disk 10c comprises a biodegradable polymer containing a therapeutic agent distributed
 2 substantially homogeneously throughout the volume thereof. Two or more such disks 10c
 3 may be stacked, as shown in Figure 1d, and bonded to one another in the manner
 4 indicated in embodiment 10d in Figure 1d.

5 Figure 1e shown a rectangular tile 10e comprised of a biodegradable
 6 polymer and a therapeutic agent. The tile embodiment 10e is designed to be received
 7 within, and adhered to, a mating receptacle within the flat outer surface of a prosthesis
 8 such as a bone plate. Figure 1f shows a rod embodiment 10f of the device comprising a
 9 plurality of cylindrical embodiments 10a of the device stacked end-to-end and bonded to
 10 one another in the manner indicated. If the cylinders 10a have an axial bore therewithin
 11 (not shown), a tubular embodiment (not shown) can be formed. The cylinders 10a
 12 comprising the rod embodiment 10f may comprise the same or different therapeutic
 13 agents and the same or different biodegradable polymer compositions. Rod embodiment
 14 10f may be inserted within a cylindrical recess in a prosthesis thereafter to sequentially
 15 release different therapeutic agents or the same therapeutic agent at different release rates
 16 following implantation within the body. Figure 10g illustrates an "O-ring" embodiment
 17 10g of a modular device. The O-ring embodiment 10g may be stacked as indicated in the
 18 "poly O-ring" embodiment 20 of Figure 2. A tapered plug embodiment 10h of a device in
 19 accordance with the present invention is shown in Figure 1h. A tubular modular
 20 embodiment of the device is indicated at 10i in Figure 1i. Figure 1j shows a threaded
 21 cylindrical embodiment 10j of the device.

1 It is to be understood that any of the solid embodiments illustrated hereinabove
2 may be hollowed out to increase the surface area of the device in contact with body fluids
3 and tissue and increase the rate of release of a therapeutic agent therefrom. A capped
4 tubular embodiment 30 of the device is shown in exploded elevational view in Figure 3.
5 The tubular body portion 31 of the device 30 comprises a plurality of tubular
6 embodiments 10i adhered to one another. The open ends of the body portion 31 are sealed
7 with caps 32 to provide a chamber 33 therewithin. Similarly, the capsular embodiment
8 10b of the drug delivery device can comprise a fillable device as shown in Figure 4. The
9 hollow capsular embodiment 40 of a drug delivery device in accordance with the present
10 invention includes a cylindrical, biodegradable body 41 and a cap 42. The biodegradable
11 polymeric material comprising the body 41 and cap 42 may include a first therapeutic
12 agent incorporated therein which is slowly released during biodegradation of the body.
13 The capsular embodiment 40 further includes a chamber 43 therewithin into which a
14 second therapeutic agent may be placed for dispensation after the body has biodegraded.
15 In embodiments 30 and 40, both the polymeric composition comprising the body portion
16 or the chamber may include a therapeutic agent therewithin.

17 It may be desirable to employ any of the foregoing embodiments of a modular
18 drug delivery device for the controlled, localized release of a therapeutic agent to soft
19 tissue. Any of the above-described modular drug delivery devices, either alone or in
20 combination, can be placed in a mesh or porous container for implantation within the
21 body as shown at numeral 50 in Figure 5. Figure 5 is a perspective view of a capsular

1 drug delivery module 10b disposed within an implantable mesh bag 51. Other geometries
 2 of drug delivery modules such as one or more spherical beads may also be placed within
 3 the mesh bag prior to implantation. The mesh may comprise a durable (i.e.,
 4 nonbiodegradable), biocompatible material such as **Dacron®** or **Gortex®**, or it may
 5 comprise a less durable, biocompatible, biodegradable polymer. If a biodegradable
 6 polymer is used to fabricate the mesh, the polymer or copolymer should be selected to
 7 persist until the module(s) contained therewithin are biodegraded. The mesh bag 51
 8 provides attachment means for suturing the device to a soft tissue or bone fastener in
 9 order to securely position the device 50 adjacent a targeted release site during
 10 biodegradation thereof and release of the therapeutic agent contained therewithin.

11 Various methods for forming bioabsorbable polymer-therapeutic agent
 12 composites are known in the art. For example, U.S. Patents 5,268,178 and 5,681,873
 13 disclose methods for making such composites. A first method for making implantable
 14 modular drug delivery devices is to dissolve a selected biodegradable polymer, such as
 15 polylactic acid, preferably obtained in the form of a powder, in a ketone solvent such as
 16 acetone or hexafluoropropanone. After the polymer has dissolved, the therapeutic agent is
 17 added in the desired proportion, and the solution is dried to form a thin layer. These steps
 18 are repeated, forming a multiple layer, laminate material comprised of the biodegradable
 19 polymer and the therapeutic agent. The laminate material can then be molded, extruded
 20 or compressed into a desired shape, such as a cylinder, tube or an annular disk, to provide
 21 a shaped module. The shaped module may be hardened by dipping it in acetone and

1 drying it until it is hard. It is also desirable to sterilize the implant with electron beam or
2 gamma radiation before placing it in a receiving recess in a prosthesis prior to
3 implantation.

4 In another method, the bioabsorbable polymer and one or more crystallization-
5 controlling agent, and/or other additives, as desired, are compounded by melting the
6 polymer and combining the other ingredients of the formulation with the molten polymer.
7 The crystallization-controlling agent, and/or other additives, may be added to the molten
8 polymer. The melting temperature for a particular bioabsorbable polymer will vary with
9 the molecular weight and/or the structure of the polymer, which information is known in
10 the art. It is preferred that a suitable polymer for compounding by this method have a
11 melting temperature less than 100 °C. A polymer having a lower melting temperature
12 will have a higher viscosity, which aids in keeping certain ingredients suspended in the
13 mix.

14 The molten mixture is cooled or annealed under controlled conditions to achieve
15 the desired physical properties for the composition, namely, moldable and cohesive. The
16 cooling or annealing temperature is preferably about 10 °C below the melting
17 temperature, and the cooling or annealing time is about 1-72 hours, preferably about 12-
18 24 hours. The composition is then allowed to cool to room temperature. Properly mixed
19 and cooled or annealed compositions are characterized as being cohesive with a uniform,
20 or homogenous consistency throughout its mass. Homogeneity of the physical properties
21 of the composition requires a substantially uniform distribution of crystalline regions of

1 polymer throughout the composition. The overall amount of crystallinity, the number and
2 size of the crystalline regions plus the degree of order in the crystalline regions will also
3 affect the physical properties of the composition.

The therapeutic agent may be added to the composition during the compounding process while the polymer, and optional crystallization-controlling agents are in a molten state, while the composition is cooling, or after the composition has cooled. If the bioactive agent is added after the composition has cooled, it may be incorporated into the composition by kneading the biologically-active agent and cooled composition together. Once the composition is placed into the prosthesis and the prosthesis implanted within the body, the biologically-active agent is released into the adjacent tissue fluids, preferably at a controlled rate.

The release of the biologically-active agent from the matrix of the composition may be varied, for example, by the solubility of the biologically-active agent in aqueous tissue fluids, the distribution of the bioactive agent within the matrix, the size, shape, porosity, solubility and biodegradability of the composition, the type and amount of crystallization-controlling agent and/or an additive, and the like. The relative amounts of bioabsorbable/biodegradable polymer in the implantable modular drug delivery device in accordance with all of the embodiments of the present invention may vary widely, depending on the rate of dissolution of the polymer (and, therefore, the rate of drug release) desired. The polymer composition includes the therapeutic agent in an amount effective to provide the desired level of biological, physiological, pharmacological and/or

1 therapeutic effect in the animal. There is generally no critical upper limit on the amount
 2 of the therapeutic agent included in the composition. The only limitation is a physical
 3 limitation for advantageous application (i.e., the therapeutic agent should not be present
 4 in such a high concentration that the consistency and handling of the composition is
 5 adversely affected). The lower limit of the amount of therapeutic agent incorporated into
 6 the composition will depend on the activity of the therapeutic agent and the period of
 7 time desired for treatment.

8 A variety of antibiotic drugs can be used in the implants to treat or prevent
 9 infection. Suitable antibiotics include many classes, such as aminoglycosides, penicillins,
 10 semi-synthetic penicillins, cephalosporins, doxycycline, gentamicin, bacitracin,
 11 vancomycin, methicillin, cefazolin and quinolones. Clindamycin has been reported to
 12 release readily from composites comprising polylactic acid. Anti-inflammatory agents
 13 such as hydrocortisone, prednisone, and the like may comprise the therapeutic agent.
 14 Substances useful for promoting growth and survival of cells and tissues or augmenting
 15 the functioning of cells, as for example, a nerve growth promoting substance such as a
 16 ganglioside, a nerve growth factor; a hard tissue growth promoting agent such as an
 17 osteoinductive growth factor, are also possible therapeutic agents suitable for
 18 incorporation within a modular drug delivery device of the present invention. The protein
 19 lactoferrin, an iron scavenger, has recently been shown to prevent the buildup of
 20 "biofilms" comprising bacterial colonies. The incorporation of lactoferrin into an

1 implantable modular drug delivery system may be useful for preventing the formation of
2 harmful biofilms at a surgical site.

3 The weight ratio of biodegradable material to antibiotic is preferably between
4 about 50:1 and about 5:1, and is most preferably about 10:1. Other pharmaceutically
5 acceptable drugs, additives, or excipients can also be included in the implantable modular
6 drug delivery devices. The modular drug delivery devices are preferably shaped to be
7 received within a mating recess in an implantable prosthesis, thereafter to be affixed to
8 the prosthesis and become integral therewith. The affixation means can be an adhesive
9 such as methacrylate or the drug delivery device can be threaded and screwed into
10 a tapped hole within a prosthesis.

11 The rate of release of a therapeutic agent from the modular drug delivery device
12 generally depends on the concentration of the therapeutic agent in the composition and
13 the choice of bioabsorbable polymer. For a particular polymer, the rate of release may
14 further be controlled by the inclusion of one or more additives that function as a release
15 rate modification agent, and by varying the concentration of that additive. The release rate
16 modification additive may be, for example, an organic substance which is water-soluble
17 or water insoluble. Useful release rate modification agents include, for example, fatty
18 acids, triglycerides, other like hydrophobic compounds, organic solvents, and plasticizing
19 compounds.

20 While particular embodiments of the present invention have been illustrated and
21 described, it would be obvious to those skilled in the art that various other changes and

1 modifications can be made without departing from the spirit and scope of the invention.
2 For example, any of the solid embodiments discussed herein can include a cavity
3 therewithin that may contain a therapeutic agent. Similarly, different modules of the
4 solid, modular drug delivery devices such as, for example, the disk embodiment 10c, may
5 contain different therapeutic agents and/or comprise different polymer blends offering
6 different biodegradation rates and be attached to one another to form a composite device.
7 It is therefore intended to cover in the appended claims all such changes and
8 modifications that are within the scope of this invention.

9 What we claim is:
10

CLAIMS

1. A modular implantable drug delivery device adapted to be received within a shaped recess within an outer surface of an implantable prosthesis wherein the outer surface of the prosthesis has a surface contour, said device being operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal, the device comprising:
 - (a) A solid module comprising a biodegradable polymer dimensioned to fit snugly within the shaped recess in the prosthesis; and
 - (b) A therapeutic agent that is released into the body of the animal during biodegradation of said biodegradable polymer.
2. The device of claim 1 wherein when said solid module comprising a biodegradable polymer is received within the shaped recess of the implantable prosthesis, the contour of the outer surface of the prosthesis is not substantially altered.
3. The device of claim 1 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.
4. The device of claim 2 wherein said solid module comprising a biodegradable polymer is affixed to said prosthesis.
5. The device of claim 1 wherein said therapeutic agent is contained within a cavity in said solid module.

- 1 6. The device of claim 2 wherein said therapeutic agent is contained within a cavity
2 in said solid module.
- 3 7. The device of claim 1 comprising a plurality of solid modules.
- 4 8. The device of claim 7 wherein said plurality of solid modules are affixed to one
5 another.
- 6 9. An implantable modular drug delivery device comprising: (a) a mesh container;
7 and (b) at least one solid module comprising a biodegradable polymer and a
8 therapeutic agent contained within said mesh container.

TITLE: Bioabsorbable Plugs Containing Drugs
INVENTORS: James Ralph and Steve Tatar
Docket No.: 02 RAL1

ABSTRACT

Bioabsorbable modular drug delivery devices having shapes and sizes adapted to be inserted within a mating receptacle on the surface of an implantable prosthesis are disclosed. The devices may be attached to one another to create custom drug delivery devices having controllable drug release characteristics that depend on the composition of individual modules comprising the device. The modules may be cylinders, disks, tiles or tubes comprised of a bioabsorbable polymer and a therapeutic agent. The therapeutic agent(s) may be homogeneously distributed throughout the polymeric body of the device or contained within a cavity within a module comprising the device, or both. The device(s) may be threaded or attached to a prosthesis by a biodegradable adhesive. The modular devices may also be formed into tapered plugs for insertion into a mating receptacle. In another embodiment, the drug delivery device may be inserted within a mesh bag that may be attached to a soft tissue as, for example, by sutures, for localized controlled dispensation of a therapeutic agent.

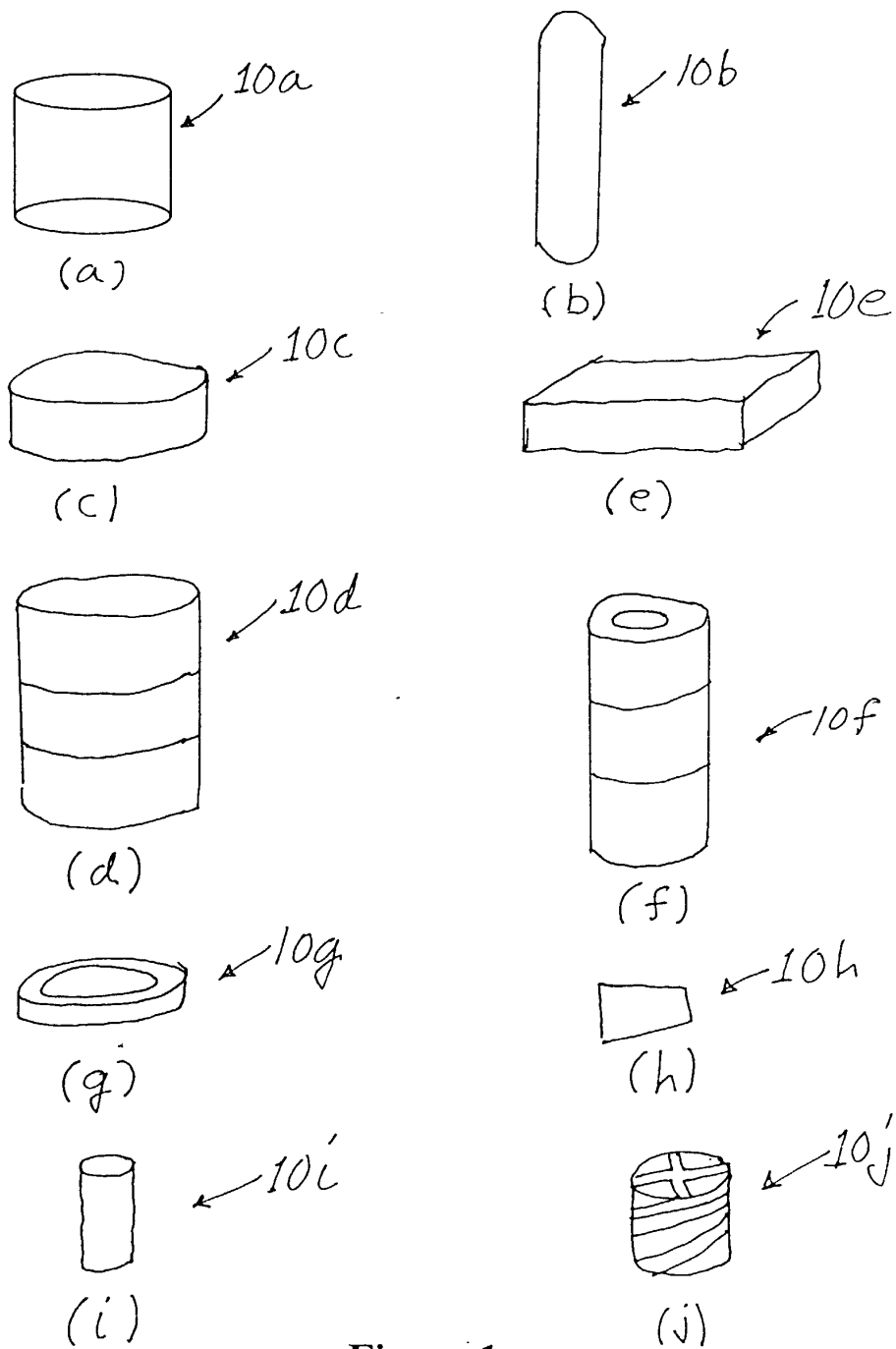


Figure 1

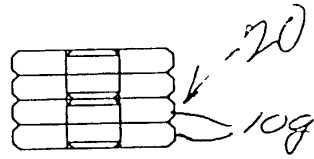


Figure 2

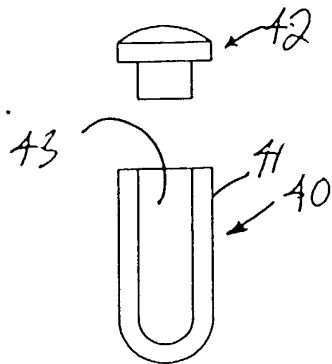


Figure 4

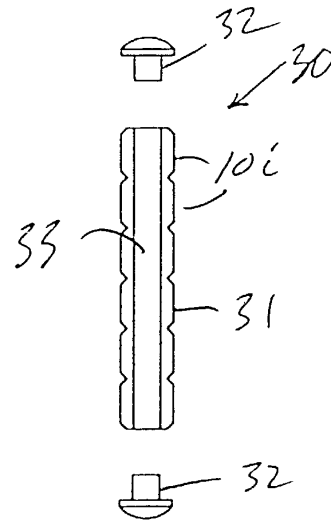


Figure 3

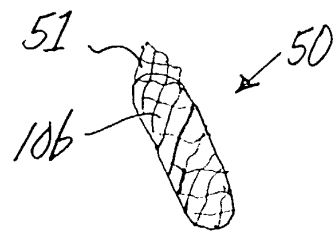


Figure 5

COMBINED DECLARATION AND POWER OF ATTORNEY

Attorney's Docket No.: 02RAL1

PATENT

As a below-named inventor, I HEREBY DECLARE THAT:

This Declaration is for the following type application: ☒ **ORIGINAL**; ☐ DESIGN; ☐ CONTINUATION;
☐ DIVISIONAL; ☐ CIP; ☐ National Stage of PCT; ☐ SUPPLEMENTAL.

My residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled : **Bioabsorbable Plugs Containing Drugs**, the specification of which (check one) : ☒ **is attached hereto**; ___ was filed on ___ as Application Serial No. ___ and was amended on (or amended through ___ , if applicable); ___ was described and claimed in PCT International Application No. ___ filed on ___ and as amended under PCT Article 19 on ___ (if any).

I hereby state that I have reviewed and understand the contents of the specification, claims, and any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations § 1.56 (a).

I hereby claim Foreign priority benefits under Title 35, united States Code § 119 of any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) designating at least one country other than the United States of America or filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

☒ **No such applications have been filed;**

☐ such applications have been filed as follows
(see attached page)

<u>Prior Foreign Application(s)</u>		<u>Month/Day</u>		<u>Priority Claimed</u>	
				<u>Under 35 USC 119</u>	
Country: _____	Number: _____	Year Filed: _____	Yes _____	No _____	
Country: _____	Number: _____	Year Filed: _____	Yes _____	No _____	
Country: _____	Number: _____	Year Filed: _____	Yes _____	No _____	

POWER OF ATTORNEY

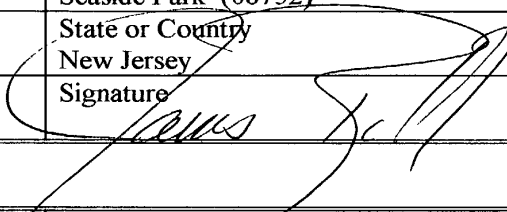
I hereby appoint Michael G. Petit, Registration No. 30, 795, as my attorney with full powers of substitution and revocation, to prosecute his application and transact all business in the Patent and Trademark Office connected herewith.

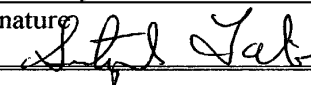
Send correspondence to:
Phone: (805) 563-6556
Fax: (805) 563-6615

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Santa Barbara, CA 93190-1929

DECLARATION

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

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State or Country New Jersey	State or Country New Jersey
Date 7-16-02	Signature 

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City (Zip) Montville (07045)	City (Zip) Montville (07045)
State or Country New Jersey	State or Country New Jersey
Date 7-16-02	Signature 

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2001

Application or Docket Number

022AC1

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	9	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	9 minus 20= *	0
INDEPENDENT CLAIMS	2 minus 3= *	0
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY
TYPE ☐

OTHER THAN
SMALL ENTITY

RATE	FEE
BASIC FEE	370.00
X\$ 9=	
X42=	
+140=	
TOTAL	370

RATE	FEE
BASIC FEE	740.00
X\$18=	
X84=	
+280=	
TOTAL	

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus **	=
	Independent	* Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM		☐

SMALL ENTITY OR

OTHER THAN
SMALL ENTITY

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL	
ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus **	=
	Independent	* Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM		☐

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL	
ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
AMENDMENT C	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
	Total	* Minus **	=
	Independent	* Minus ***	=
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM		☐

RATE	ADDITIONAL FEE
X\$ 9=	
X42=	
+140=	
TOTAL	
ADDIT. FEE	

RATE	ADDITIONAL FEE
X\$18=	
X84=	
+280=	
TOTAL	
ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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