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First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_SIDS.pdf	1035758	no	5
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	16448357
	Filing Date	2019-06-21
	First Named Inventor	F. Barry Bays
	Art Unit	3775
	Examiner Name	TRUONG, KEVIN THAO
	Attorney Docket Number	71212.4.8.6

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	2	4959066	A	1990-09-25	DUNN et al.	
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STATEMENT BY APPLICANT**
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Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1	2006158972	JP	A	2006-06-22	DEPUY PRODUCTS INC	English Abstract Submitted	

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STATEMENT BY APPLICANT**
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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2020-07-14
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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Bibliographic data: JP2006158972 (A) — 2006-06-22

BONE SHAPING INSTRUMENT AND METHOD FOR USING THE SAME

Inventor(s): BENNETT TRAVIS; WYSS JOSEPH G ± (BENNETT TRAVIS, ; WYSS JOSEPH G)

Applicant(s): DEPUY PRODUCTS INC ± (DEPUY PRODUCTS INC)

Classification: - international: **A61B17/16; A61B17/56**
- cooperative: **A61B17/1764 (EP); A61B17/154 (EP)**

Application number: JP20050352322 20051206 Global Dossier

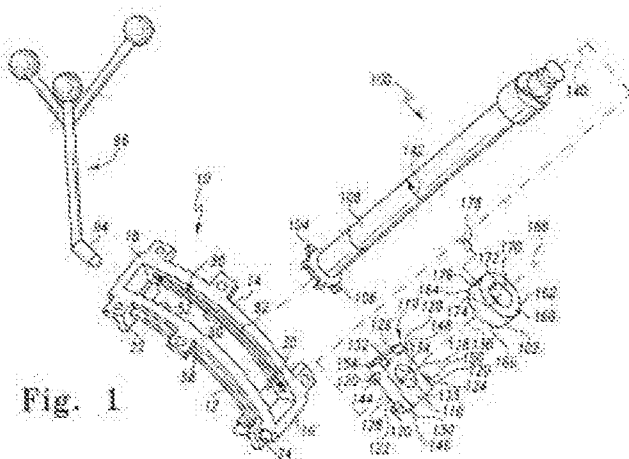
Priority number (s): US20040005798 20041207

Also published as: AT401039 (T) AU2005234717 (A1) AU2005234717 (B2)
EP1669034 (A1) EP1669034 (B1) US2006122616 (A1)
US7766913 (B2) less

Abstract of JP2006158972 (A)

PROBLEM TO BE SOLVED: To provide a cutting tool configured to cut a bone according to a guide so that the bone can receive a surface replacement implant.

SOLUTION: A bone resection instrument for resecting an end of the bone along a surface having a curvature comprises the guide, the cutting tool and a track follower. The guide is configured to be removably attached in a fixed position to the end of the bone. The guide is also configured to include a track having a curvature generally corresponding to the curvature of the surface to be resected in the bone. The cutting tool has a cutting face. The track follower is configured to couple to the cutting tool and cooperate with the track to facilitate reciprocation of the cutting tool relative to the guide to induce the cutting face to resect the bone along the surface having the curvature. A method is further provided for resecting a bone along a curved



surface conformed to the curvature of a curved surface of the underside of a prosthetic component. ;COPYRIGHT: (C)2006,JPO&NCIP

(19) 日本国特許庁(JP)

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 (33) 優先権主張国 米国(US)

(71) 出願人 501384115
 デビュー・プロダクツ・インコーポレイテッド
 アメリカ合衆国インディアナ州46581
 ワーソー・オーソピーディックドライブ7
 00
 (74) 代理人 100066474
 弁理士 田澤 博昭
 (74) 代理人 100088605
 弁理士 加藤 公延
 (74) 代理人 100123434
 弁理士 田澤 英昭
 (74) 代理人 100101133
 弁理士 濱田 初音

最終頁に続く

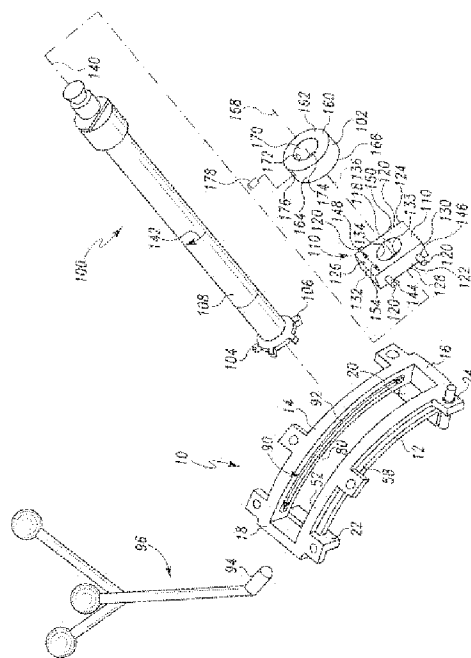
(54) 【発明の名称】 骨整形器具およびその使用方法

(57) 【要約】

【課題】骨が表面置換インプラントを受容できるようにガイドに従ってその骨を切削するように構成された切削器具を提供すること。

【解決手段】曲率を有する表面に沿って骨の端部を切除するための骨切除器具であって、ガイド、切削器具、およびトラックフォロアを含む。このガイドは、骨の端部に対して固定位置に取り外し可能に取り付けできるように構成されている。ガイドはまた、骨の切除する表面の曲率に概ね一致する曲率を有するトラックを含むように構成されている。切削器具は切削面を有する。トラックフォロアは、切削器具に結合し、トラックと協働して、ガイドに対する切削器具の往復運動を容易にし、切削面が曲率を有する表面に沿って骨を切除できるように構成されている。プロテーゼコンポーネントの下側の曲面の曲率に一致する曲面に沿って骨を切除する方法も提供する。

【選択図】 図1



【特許請求の範囲】

【請求項1】

曲率を有する表面に沿って骨の端部を切除するための骨切除器具であって、
前記骨の端部に対して取り外し可能に固定位置に取り付けでき、かつ前記骨の切除する表面の曲率に概ね一致する曲率を有するトラックを含むように構成された、ガイドと、
切削面を有する切削器具と、
前記切削器具に結合するように構成され、かつ前記トラックと協働して前記ガイドに対する前記切削器具の往復運動を容易にし、前記切削面が前記曲率を有する上面に沿って骨を切削するように構成されたトラックフォロアと、を含む、骨切除器具。

【請求項2】

請求項1に記載の骨切除器具であって、
前記切削器具に結合されたシャフトをさらに含み、このシャフトが、前記切削器具と協働して前記切削面が骨を切削するように構成されている、骨切除器具。

【請求項3】

請求項2に記載の骨切除器具であって、
前記シャフト、前記切削器具、前記トラックフォロア、および前記ガイドが、協働して前記曲率を有する表面に対して概ね垂直に前記シャフトを維持する、骨切除器具。

【請求項4】

請求項3に記載の骨切除器具であって、
前記シャフトに結合して前記シャフトをその長軸を中心に回転させるドライバをさらに含む、骨切除器具。

【請求項5】

請求項4に記載の骨切除器具であって、
前記シャフトは、前記切削面に固着されている、骨切除器具。

【請求項6】

請求項5に記載の骨切除器具であって、
前記トラックフォロアおよび前記トラックは、前記切削器具が前記ガイドに対して前記トラックに沿って往復運動し易くするように構成されている、骨切除器具。

【請求項7】

請求項6に記載の骨切除器具であって、
前記切削面は、その端部および側面で切削するように構成されている、骨切除器具。

【請求項8】

請求項5に記載の骨切除器具であって、
前記ガイドは、前記曲率を有する表面に沿ってその上に延在する離間したレールを含み

、
前記レールは、前記トラックを画定するよう協働する、骨切除器具。

【請求項9】

請求項8に記載の骨切除器具であって、
湾曲スロットが前記各レールを通るように形成され、前記湾曲スロットが協働して前記トラックを画定している、骨切除器具。

【請求項10】

請求項8に記載の骨切除器具であって、
前記シャフトの一部が前記離間したレール間に配置されている、骨切除器具。

【請求項11】

請求項9に記載の骨切除器具であって、
前記シャフトの一部が前記離間したレール間に配置されている、骨切除器具。

【請求項12】

請求項11に記載の骨切除器具であって、
前記シャフトは、前記湾曲スロットの接線に垂直な前記シャフトの長軸に沿って往復運

動するように構成されている、骨切除器具。

【請求項13】

請求項12に記載の骨切除器具であって、

前記シャフトにストッパーが形成されており、このストッパーが、前記トラックフォロアと協働して前記シャフトの骨に向かう往復運動を制限する、骨切除器具。

【請求項14】

請求項13に記載の骨切除器具であって、

前記ストッパーは、前記シャフトに対して長手方向に調節できるように構成されている

【発明の詳細な説明】

【開示の内容】

【0001】

〔発明の分野〕

本発明は、関節形成術に関連し、詳細には、関節置換システムのコンポーネントを受容するように骨を整形する器具および技術に関する。

【0002】

〔背景および概要〕

損傷した関節や悪化した関節を置換するためにプロテーゼ関節コンポーネントが用いられることは良く知られている。通常の関節置換術では、関節が置換される肢の長さを変えることなくプロテーゼ装置を骨に確実に取り付けできるように、置換される関節を構成する1または複数の骨の遠位端部または近位端部を切除する必要がある。関節コンポーネント製造者は、切開部が小さく、運動学的により適切なインプラントを用いる、低侵襲性外科手術を必要とする関節置換術から恩典が得られることを認識している。加えて、若い患者が関節置換術を受けるようになってきたため、患者が術後に早期に回復し、優れた機能が得られ、より耐久性が得られる関節置換術が要望されている。

【0003】

運動学的に適切で耐久性に優れたインプラントにとって、骨とインプラントの接触面が重要である。プロテーゼが最終的に機能しなくなって、さらなる骨切除を行うプロテーゼ置換術が必要になる可能性がある。従って、インプラントを骨に適切に配置できるようにするため、およびインプラントへの骨の内植および／または成長を促進するために骨を十分に切除するのが好ましいが、修正術またはインプラントの置換のためにさらなる骨の切除ができるように切除する骨の量を少なくすべきである。インプラントを適切に配置するために骨を十分に切除することと、インプラントの修正または置換を行い易いようにするために切除する量を少なくすることとの矛盾する考えに対処するべく、ある方法では表面置換インプラントが用いられる。表面置換インプラントには、平坦な表面ではなく湾曲した表面または複数の非同一直線表面に骨を整形する必要がある。大きさが最小で、切削器具を正確に案内して表面置換インプラントを受容する曲面を形成する、インプラント受容のために骨の関節運動面を切除する器具を提供するのが好ましい。

【0004】

一般的に用いられている1つのタイプの表面インプラントは、単一区画膝関節システムである。脛骨（下肢の骨）と大腿骨（腿の骨）が膝で交わり、内側および外側の脛骨-大腿骨区画に分離されている。膝前部の膝蓋骨（膝の蓋）が大腿骨の滑車（膝の窩）と関節運動して膝蓋骨-大腿骨区画を形成する。脛骨-大腿骨区画は歩行に用いられる。膝蓋骨-大腿骨区画は、屈曲する時、しゃがむ時、そして階段の昇降の時に用いられる。単一区画膝関節形成術では、通常は内側である膝の脛骨-大腿骨区画の1つの表面が再形成される。これは、脛骨-大腿骨区画および膝蓋骨-大腿骨区画の両方の表面を再形成する全膝関節形成術（TKA）とは対照的である。単一区画膝関節形成術（UKA）の普及に伴い、器具およびインプラントのデザインの両面から保存的な方法を提供するプロテーゼシステムが重要である。

【0005】

すべての再建術において、年齢および活動レベルを考慮すべきである。一般に、関節炎

の状態により治療法が決まる。単一区画膝関節形成術を支援する低侵襲性技術の進歩により、生活に支障をきたすような関節炎の苦痛からの救済や早期回復の利点などのために多数の患者にこの代替法が提案されてきた。一部の患者で、通常は内側である膝の一部分に著しい関節炎の変化が見られる。膝の外側すなわち膝蓋骨の下側に他の大きな関節炎の変化がない場合は、部分膝関節置換術（正式には、「単一区画膝関節置換術（uni-compartmental knee replacement）」と呼ぶ）で十分である。単一区画膝関節置換術は、低侵襲性の部分膝関節置換術である。

【0006】

全膝関節形成術に対する単一区画膝関節形成術の利点には、（１）早期回復、（２）痛みが少ない、（３）可動範囲が広い、（４）正常という感覚が大きい、（５）プロテーゼが磨耗した時に選択肢が多い、（６）輸血が必要ない、（７）抗凝固剤が必要ない、などが含まれる。単一区画膝関節形成術による利点には、外科手術が大掛かりでない、切開部が小さい、TKAよりも組織の外傷が少ない、が含まれる。初めのTKAは、通常は１０年～１５年もつ。機能しなくなったら、修正TKA（RTKA）で置換しなければならない。RTKAは、合併症の発症率が高く、初めのTKAほど長持ちしない。単一区画膝関節形成術は時間を稼ぐことができる。プロテーゼが磨耗したらTKAで置換できる。患者はRTKAを受ける必要がなく、仮にRTKAを受ける場合も、TKAにより何年も延ばすことができる。TKAの代わりに単一区画膝関節形成術を行うと、年齢に関係なく、患者はその恩恵を受けられる。高齢の患者は、外科手術が軽くなり、早期回復の恩恵を享受することができる。若年の患者は、プロテーゼが最終的に使用できなくなった場合（全てのプロテーゼは若い患者でより寿命が短い）、あまり好ましくないRTKAではなく好ましい初めのTKAを受けることができる。

【0007】

ある従来技術による単一区画膝関節システムでは、器具の使用に制限があり、再現可能な整合が困難であり、より侵襲性の高い外科手術が必要となる嵩張る器具が必要である。従来技術による２、３の単一区画膝関節システムは、最小限の切開で再現可能な結果が得られる骨保存的な大腿骨コンポーネントおよび脛骨コンポーネントでデザインされている。表面再形成大腿骨インプラントは、現在の完全切除大腿骨インプラントに比べて高い質で骨を温存できる。

【0008】

このような単一区画膝関節システムの一例として、デピュイ・オーソピーディックス（DePuy Orthopaedics）が販売するPRESERVATION（商標）単一区画膝関節を挙げることができる。PRESERVATION（商標）単一区画膝関節では、外科医が、固定式または可動式の支持脛骨を患者によって選択できる。このシステムは、関節線の修復、荷重分割バランス、およびコンポーネントの整合を行う器具を用いて低侵襲性法をサポートする。PRESERVATION（商標）単一区画膝関節システムでは、後に任選択の全膝関節形成術における骨切除を最小限にする技術を利用する。このシステムは、コンピュータ支援外科手術（CAS）法を利用できるように適合されている。

【0009】

低侵襲性の単一区画膝関節外科手術の技術的な問題が、関節形成術専門医でさえも一層明らかになってきた。CAS法は、明らかに低侵襲性外科手術に一定の役割を果たしている。CAS法は、切開部の長さに関係なく、外科的な視野を拡大して重要な人体の目印を最適に視覚化する。CAS法では、CASを用いない低侵襲性法での達成が困難な一定レベルの視野と制御を外科医が得られる。重要な人体構造が完全に視覚化されれば、指先操作の器具の調節により、外科医が画面上のプランニングを非常に正確にテーブルに移すことができる。CAS法に用いられている仮想プランニングおよび運動学的評価ソフトウェアにより、骨を切除する前に各患者に対してインプラントの位置合わせを行うことができる。

【0010】

本発明は、ガイド、および骨が表面置換インプラントを受容できるようにそのガイドに

従ってその骨を切削するように構成された切削器具を提供する。このガイドは、表面置換プロテーゼを受容するための所望の深さの切削に十分な自由を提供しつつ、切削器具の適切な整合を維持するための構造を含む。ガイドおよび切削器具は、一貫した結果に必要な整合ガイドを外科医に提供すると共に、最小切開法に効果的に用いることができるように構成されている。この開示するガイドは、C A S法に利用できるように構成されている。従って、最小切開法でも再現性のある結果が可能となる。

【0011】

本開示の一態様に従えば、曲率を有する表面に沿って骨の端部を切除する骨切除器具は、ガイド、切削器具、およびトラックフォロアを含む。ガイドは、骨の端部に対して固定位置に取り外し可能に取り付けることができるように構成されている。ガイドはまた、骨の切除する表面の曲率に概ね一致した曲率を有するトラックを含むように構成されている。切削器具は切削面を含む。トラックフォロアは、切削器具に結合されてトラックと協働してガイドに対する切削器具の往復運動を容易にし、切削面が曲率を有する表面に沿って骨を切除できるように構成されている。

【0012】

本開示の別の態様に従って、プロテーゼコンポーネントの下側の曲面の曲率に一致する曲面に沿って骨を切除する方法を提供する。この方法は、骨の表面を覆う組織を切開するステップと、切除する骨の表面に沿ってガイドを配置するステップと、ガイドを骨に固定するステップと、切削面を有するカッターをガイドに相互連結するステップと、曲面の接線に概ね平行に切削面を維持するステップと、トラックに沿ってカッターを案内しながら切削面を骨に沿って横断させるステップと、を含む。組織を切開するステップでは、切除する骨の表面を覆う組織を低侵襲的に切開する。配置するガイドは、プロテーゼコンポーネントの下側の曲面の曲率に一致するように構成されているトラックを含む。

【0013】

本明細書に含まれその一部をなす添付の図面は、本発明の好適な実施形態を例示しており、後述の説明と共に参照すれば、本発明の原理をより良く理解できるであろう。添付の図面および後述の説明は、もちろん単なる例示目的であり、本発明を制限するものではないことを理解されたい。

【0014】

〔詳細な説明〕

限定目的ではない添付の図面を用いて例示的な装置を説明する。全ての図面において、同じ参照記号は同じ構成要素を示し、類似の参照記号は類似の構成要素を示す。

【0015】

本発明の原理をより良く理解できるように、図面に例示し後述する実施形態について説明する。従って、本発明の範囲を限定することを意図するものではないことを理解されたい。さらに、本発明は、例示した実施形態のあらゆる代替形態および変更形態を含み、当業者であれば容易に想到するような本発明の原理のさらなる適用例も含むことを理解されたい。

【0016】

開示する骨整形器具を用いると、下側が曲率を有する表面を含むように改変されたジョンソン・アンド・ジョンソン社のデピュイ・オーソピーディックス (DePuy Orthopaedics) が販売する P R E S E R V A T I O N (商標) 単一区画膝関節の改変大腿骨コンポーネントなどの表面置換インプラントを受容できるように骨を準備するのが容易である。この器具は、膝関節形成術のために遠位大腿骨顆または滑車の準備ができるように構成されている。この器具は、曲面の矢状切除および冠状切除の両方を行うことができる。

【0017】

骨整形器具の一実施形態では、端部および側面切削器具が、トラックガイドによって案内されそのトラックガイド内を骨に対して移動する。切削深さは、ガイドに係合する切削器具の深さストッパー、および伸長可能またはシムを用いて効果的に伸長できるガイドの脚の長さによって制御される。深さストッパーは、骨整形器具によって形成される切削面

の曲率の半径も制御する。従って、深い切削が必要だが切削面の曲率半径を小さくする必要がない場合は、ガイドの脚の長さを短くして切削深さを調節することができる。しかしながら、小さい曲率半径を必要とする深い切削が望ましい場合は、切削深さは、切削器具の切削面から離れるように深さストッパーを切削器具のシャフトに対して移動させて調節すべきである。

【0018】

深さストッパーは、外科医が切削の深さおよび曲率半径を選択できるように切削器具に対して長手方向に調節できるように構成されている。深さストッパーおよびガイドは、切削器具がガイド内を移動する間、切削器具を適切な向きに維持するように構成されている。例示されている実施形態では、深さストッパーおよびガイドは、ガイド内に形成されたガイドトラックに対して垂直に切削器具を維持するように構成されている。

【0019】

ガイドの第1の実施形態と共に使用する切削器具の第2の実施形態では、2つのラスプが、ガイドによって案内されながらハンドドリルによって駆動されるように構成されている。ラスプが骨の表面を往復運動して、所望の切削形状が形成される。例示されている切削器具はそれぞれ、低侵襲性切開部を用いる外科手術に骨整形器具を使用し易いように可撓性の駆動軸によって駆動されるように構成されている。

【0020】

本開示では各誘導切削器具およびガイドの各実施形態について1つの大きさのみを記載しているが、当業者であれば、膝関節プロテーゼシステムは通常、複数の異なった大きさの大腿骨コンポーネントを含むため、このようなシステムには、適切に構成された適切な大きさの複数のガイドおよび誘導切削器具が含まれることを理解できるであろう。従って、開示するガイドおよび誘導切削器具は、これらのガイドおよび誘導切削器具に関連する単一区画膝関節プロテーゼシステムの大腿骨コンポーネントを用いて説明する。

【0021】

例えば図1 - 図11、詳細には図1 - 図4に示されているように、ガイド10の第1の実施形態は、内側レール12、外側レール14、後側交差部材16、前側交差部材18、後脚19、前脚21、および複数の耳24、26、28、30、32、および34を含む。後側交差部材16は、内側レール12の後端部36と外側レール14の後端部38との間に延在し、これらを結合している。前側交差部材18は、内側レール12の前端部40と外側レール14の前端部42との間に延在し、これらを結合している。内側レール12、外側レール14、後側交差部材16、および前側交差部材18が協働して器具受容スロット44を画定している。切削器具100、200の一部が器具受容スロット44を介して延在し、かつ／または駆動源114の駆動軸112がこれらの切削器具100、200を駆動するために器具受容スロット44を介してこれらの切削器具100、200まで延びている。

【0022】

例示されている実施形態では、内側レール12と外側レール14が互いに長手方向に平行に延在し、器具受容スロット44の側壁を画定している。内側レール12と外側レール14は、器具受容スロット44の幅46を画定する変位によって互いに離間している。例示されている一実施形態では、器具受容スロット44の幅46は、低侵襲性処置で使用し易いように約13mmである。

【0023】

後側交差部材16と前側交差部材18は、互いに横方向に平行に延在し、器具受容スロット44の端壁を画定している。後側交差部材16と前側交差部材18は、器具受容スロット44の長さ48を画定する変位によって互いに離間している。

【0024】

例示的に、内側レール12は、凹状底壁50、凸状上壁52、内壁54、および外壁56を含む。内壁54と外壁56はそれぞれ、平坦であって、互いに概ね平行である。内壁54および外壁56は、凹状底壁50と凸状上壁52の間に延在し、これらを結合してい

る。凹状底壁50および凸状上壁52はそれぞれ、特定のガイド10に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0025】

内側レール12は、内壁54と外壁56との間にそれぞれ延在する凹状上壁60、凸状底壁62、後壁64、および前壁66によって画定された湾曲スロット58を含むように形成されている。凹状上壁60および凸状底壁62はそれぞれ、特定のガイド10に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0026】

凹状上壁60と凸状底壁62は、湾曲スロット58の幅68である変位によって互いに離間している。湾曲スロット58の幅は、湾曲スロット58内で前後長手方向に運動できるようにガイドピン120、214を保持する大きさである。湾曲スロット58の前壁66と後壁64は、湾曲スロット58の長さ70である変位によって互いに離間している。前壁66および後壁64は、ガイドピン120、214が湾曲スロット58内に保持された時にそれらの前後長手方向の運動を制限するストッパーとして機能する。

【0027】

内側レール12は、外壁56から外側に延びた内側後部耳24、内側中心耳26、および内側前部耳28を含むように形成されている。内側後部耳24は、内側レール12の後端部36に近接して位置する。内側前部耳28は、内側レール12の前端部40に近接して位置する。内側中心耳26は、内側後部耳24と内側前部耳28との間の内側レール12の中間付近に位置する。内側後部耳24、内側中心耳26、および内側前部耳28はそれぞれ、例えば図8-図11に示されているようにガイド10を大腿骨に固定するためにねじ31を受容するように構成されたねじ受容孔29を含むように形成されている。ねじ受容孔29は、特定のガイド10に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率の中心の焦点に向かって径方向に延びた軸を中心に同軸的に形成されている。ねじ受容孔29の向きは、ガイド10を大腿骨に固定するために低侵襲性切開部を介してねじ31を挿入し易い向きである。

【0028】

例示的に、内側レール12および外側レール14は、器具受容スロット44の中心を通るレール12、14に対して垂直に延在する平面を中心に対象に形成されている。従って、外側レール14は、凹状底壁72、凸状上壁74、内壁76、および外壁78を含む。内壁76と外壁78は、互いに概ね平行であって、凹状底壁72と凸状上壁74との間に延在し、これらを結合している。凹状底壁72および凸状上壁74はそれぞれ、特定のガイド10に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0029】

外側レール14は、内壁76と外壁78との間にそれぞれ延在する凹状上壁82、凸状底壁84、後壁86、および前壁88によって画定された湾曲スロット80を含むように形成されている。凹状上壁82および凸状底壁84はそれぞれ、特定のガイド10に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。凹状上壁82と凸状底壁84は、湾曲スロット80の幅90である変位によって互いに離間している。湾曲スロット80の幅90は、その湾曲スロット80内で前後長手方向に運動できるようにガイドピン120、214を保持する大きさである。湾曲スロット80の前壁88と後壁86は、湾曲スロット80の長さ92である変位によって互いに離間している。前壁88および後壁86は、ガイドピン120、214が湾曲スロット80内に保持された時にそれらの前後長手方向の運動を制限するストッパーとして機能する。

【0030】

外側レール14は、外壁78から外側に延びた外側後部耳30、外側中心耳32、および外側前部耳34を含むように形成されている。外側後部耳30は、外側レール14の後端部38に近接して位置する。外側前部耳34は、外側レール14の前端部42に近接し

て位置する。外側中心耳32は、外側後部耳30と外側前部耳32との間の外側レール14の中心付近に位置する。外側後部耳30、外側中心耳32、および外側前部耳34はそれぞれ、ガイド10を大腿骨に固定するためにねじ31を受容するように構成されたねじ受容孔29を含むように形成されている。

【0031】

後脚19は、ガイド10の後側交差部材16の底面から後側フット20まで径方向内側に延びている。前脚21は、ガイド10の前側交差部材18の底面から前側フット22まで径方向内側に延びている。後側フット20および前側フット22は、ガイド10が大腿骨頤の切除のために配置された時に、第2の誘導カッター200を用いて後述するシム212または大腿骨頤に係合するように構成されている。後側フット20および前側フット22がそれぞれ大腿骨頤またはシム212に係合した時に、後脚19と前脚21が協働して、内側レール12の凹状底壁50および外側レール14の凸状底壁72を大腿骨頤から離間させる。後脚19および前脚21の有効長さにより切削深さが制御されるため、これらの脚は、シムを用いない方が良い場合に伸縮自在にすることができる。別法では、複数のガイド10はそれぞれ、長さを変えることができる後脚19および前脚21を備えることができる。

【0032】

例えば図1、図4、および図8に示されているように、前脚21は、一定の向きにCAS位置確認装置96のシャフト94を受容できるように構成された孔98を含むように形成されている。CAS位置確認装置96のシャフト94が孔98内に受容されると、位置確認装置96がガイド10の向き／位置を3次元で詳細に示す。従って、CAS位置確認装置96が孔98内に受容されると、CAS技術を用いて、ガイド10を適切に配置することができる。当業者であれば、開示の範囲内でCAS位置確認装置96をガイド10に取り付けるために、別の位置に他の結合を設けることができることを理解できよう。

【0033】

誘導切削器具100の第1の実施形態は、深さストッパ102、カッター104、および保持カラー110を含む。カッター104は、切削面106およびシャフト108を含む。例示的に、カッター104は、端部および側面の切削を行う切削面106を含む。カッター104は、凹状球リーマ、凸状球リーマ、または平面リーマなどのリーマ、エンドミル、またはバーとすることができる。切削面106は、シャフト108が回転する時にそのシャフト108の長軸140を中心に回転するようにシャフト108に取り付けられている。

【0034】

例示的に、シャフト108は、駆動源114の駆動軸112に結合できるように構成されている。駆動源114は、硬質または好ましくは可撓性である駆動軸112を備えたハンドドリルとすることができる。ハンドドリルは、動力源として手動、電気、空気、または液体を用いることができる。駆動源114を、カッター104のシャフト108を回転させることができる他の装置にすることも開示の範囲内である。

【0035】

保持カラー110は、シャフト受容孔118および複数のガイドピン120を含むように形成された本体116を含む。保持カラー110の本体116は、上壁126と底壁128の間および前壁130と後壁132の間に延在し、これらをそれぞれ結合している平行に離間した側壁122、124を含む。上壁126は、平面であって、カッター104の切削深さを制限するように深さストッパ102に係合するストッパ一面として機能するように構成されている。シャフト受容孔118は、上壁126および底壁128を貫通している。例示的に、シャフト受容孔118は、上壁126に垂直な長軸136を中心に同軸的に形成された円筒側壁134によって画定されている。円筒側壁134は内径138を有する。例示的に、円筒側壁134は、内部にカッター104のシャフト108を受容するように構成され、シャフト108がその長軸140を中心に自由に回転できる大きさを有する。円筒側壁134がカッター104のシャフト108と協働し、保持カラー1

10と深さストッパー102により、カッター104の整合が維持される。従って、シャフト受容孔118の内径138は、カッター104の不整合を制限するようにカッター104のシャフト108の外径142よりも僅かに大きい。例示されている実施形態では、カッター104のシャフト108は、低侵襲性切開部を介して骨整形器具を使用し易いように径方向に延在するように整合されている。

【0036】

例示されている実施形態では、複数のガイドピン120は、保持カラー110の内側壁122から垂直に延びた内側前部ガイドピン144および内側後部ガイドピン146、並びに保持カラー110の外側壁124から垂直に延びた外側前部ガイドピン148および外側後部ガイドピン150を含む。ガイドピン120は、保持カラー110の上壁126に平行な平面を画定している。例示的に、複数のガイドピン120はそれぞれ、湾曲スロット58、80の幅68、90よりも僅かに小さい直径152を有するため、ガイドピン120が湾曲スロット58、80内に受容された時にその湾曲スロット58、80内を前後に往復運動することができる。ガイドピン120は、保持カラー110の本体116の内外にそれらの長軸に沿って往復運動できるようにばね付勢することができる。

【0037】

保持カラー110の本体116の内側壁122と外側壁124は、変位154によって離間している。内側壁122と外側壁124との間のこの変位154は、ガイド10の器具受容スロット44の幅46よりも僅かに小さいがほぼ同じである。使用の際、保持カラー110の一部が、器具受容スロット44内の前後の往復運動のためにガイド10の器具受容スロット44内に受容される。内側壁122の一部が、内側レール12の内壁54に近接して位置し、外側壁124の一部が、外側レール14の内壁76に近接して位置する。保持カラー110の内側壁122と内側レール12の内壁54および保持カラー110の外側壁124と外側レール14の内壁76が協働して、保持カラー110が器具受容スロット44内に受容された時のシャフト受容孔118の長軸136を中心とした保持カラー110の回転を制限する。器具受容スロット44内の保持カラー110の回転が制限されるため、ガイドピン120が湾曲スロット58、80内に維持される。

【0038】

例示的に、ガイドピン120は、トラックフォロアとして機能して、湾曲スロット58、80の凸状底壁62、84の曲率に一致する曲率を有する経路に従うように保持カラー110を誘導する。当業者であれば、限定するものではないが、保持カラー110の本体116から延びた壁部、ボス、耳、およびフランジを含み、湾曲スロット58、80内での前後の往復運動の際に湾曲スロット58、80内に受容され案内されるように構成された他のトラック追従装置も本開示の範囲内で利用できることを理解できよう。内側レールおよび外側レールが湾曲底壁および湾曲上壁で形成されてトラックとして機能し、保持カラーが、本体116から延び、例えば図12に示されているように湾曲底壁および湾曲上壁を従うように構成されたガイドピン、壁部、ボス、耳、およびフランジなどのトラックフォロアを含むことも本開示の範囲内である。

【0039】

使用の際、ガイドピン120は、湾曲スロット58、80内に保持されると、湾曲ガイド面すなわちトラックを画定する湾曲スロット58、80の凸状底壁62、84の上に位置する。湾曲スロット58、80の凹状上壁60、82は、ガイド10に対するガイドピン120の近位側および遠位側への運動を制限する働きをする。ガイドピン120は、湾曲スロット58、80内に位置し、特定のガイド10に関連した単一区画関節プロテーゼの大腿骨コンポーネントの内面の曲率に近い曲率に沿ってカッター104の切削面106が移動するのを制限する働きをする。

【0040】

例示されている深さストッパー102は、平面環状上壁162、円筒外壁164、および軸168と同軸的に形成された平面環状底壁166を含むように形成された円筒本体160を含む。上壁162および底壁164を貫通してその間に延在するシャフト受容孔1

70が、軸168と同軸的に形成された円筒側壁172によって画定されている。例示的に、円筒側壁172は、内部にカッター104のシャフト108を受容するように構成され、カッター104のシャフト108がその長軸140に沿って長手方向に往復運動できる大きさを有する。従って、シャフト受容孔170の内径174は、カッター104のシャフト108に沿って深さストッパー102の位置を容易に調節できるようにカッター104のシャフト108の外径142よりも僅かに大きい。止めねじ受容孔176が、深さストッパー102の本体160の外壁164および円筒側壁172を径方向に貫通している。止めねじ受容孔176は、止めねじ178を締め付けて深さストッパー102をカッター104のシャフト108に対して固定位置に固定するべく内部に止めねじ178を受容できる大きさであり、ねじが設けられている。当業者であれば、深さストッパー102の別の構造を用いて、深さストッパー102をカッター104のシャフト108に一時的または永久的に固定できることを理解できよう。

【0041】

深さストッパー102の平面環状底壁166は、保持カラー110の平面上壁126と協働して、大腿骨に対するカッター104の近位側への動きを制限し、これによりカッター104による切削深さが制限される。深さストッパー102の平面環状底壁166はまた、保持カラー110の平面上壁126に係合し、これによりカッター104のシャフト108の長軸と保持カラー110の軸136との適切な整合が促され、最大切削深さでの切削面106の適切な整合が維持される。保持カラー110の円筒側壁134がカッター104のシャフト108と協働し、保持カラー110と深さストッパー102により、他の深さでのカッター104の整合が維持される。

【0042】

例えば図5 - 図7に示されているように、誘導切削器具200の第2の実施形態は、後部カッター202、前部カッター204、後部戻しばね206、前部戻しばね208、ドライバ210、複数対のシム212、および複数のガイドピン214を含む。複数対のシム212は、後脚19および前脚21の有効長さを調節し、これにより誘導切削器具200による切削深さを調節するために、ガイド10の前側フット22および後側フット20の下側に配置するために用意されている。複数対のシム212が、後部および前部のカッター202、204での大腿骨の切削が終わった後にシム212を交換して切削深さを増分的に深くできるように増分的に異なった厚みを有する対で用意されている。

【0043】

後部カッター202は、上壁218、切削面220、内側壁222、外側壁224、後端壁226、および前端壁228を有する本体216を含む。内側壁222および外側壁224は、上壁218と切削面220の間および前壁228と後端壁226の間に延在し、これらを結合している。

【0044】

例示されている実施形態では、上壁218および切削面220は、後部カッター202に一致する単一区画膝関節プロテーゼの大腿骨コンポーネントの内面の前後の曲率に一致する前後の曲率を有する。当業者であれば、上壁218の曲率は後部カッター202の動作にとって重要ではないが、カッター202に審美性および安全性を付与することを理解されたい。従って、上壁218が平坦であることや、上壁218が切削面220とは異なる曲率を有することも開示の範囲内である。

【0045】

切削面220は、その切削面220に亘って内側 - 外側に延在する複数列の歯230を含むように形成されている。切削面220およびその切削面220に形成されている複数の歯230は、内側 - 外側に亘って平坦にしても良いし、または後部カッター202に一致する単一区画膝関節プロテーゼの大腿骨コンポーネントの内側 - 外側の曲率に一致する凹状または凸状の内側 - 外側の曲率を有するようにしても良い。

【0046】

例示されている実施形態では、複数のガイドピン214は、後部カッター202の内側

壁222から垂直に延びた内側前部ガイドピン232および内側後部ガイドピン234、並びに後部カッター202の外側壁224から垂直に延びた外側前部ガイドピン236および外側後部ガイドピン238を含む。複数のガイドピン214は、後部カッター202の切削面220の接線に平行な平面を画定している。例示的に、複数のガイドピン214はそれぞれ、湾曲スロット58、80の幅68、90よりも僅かに小さい直径240を有するため、ガイドピン214が、湾曲スロット58、80内に受容されると、湾曲スロット58、80内を前後に往復運動することができる。ガイドピン214は、後部カッター202の本体216の内外にそれらの長軸に沿って往復運動できるようにばね付勢することができる。

【0047】

後部カッター202の本体216の内側壁222および外側壁224は、変位242によって平行に離間している。内側壁222と外側壁224との間のこの変位242は、ガイド10の器具受容スロット44の幅46よりも僅かに小さいがほぼ同じである。使用の際は、後部カッター202の一部が、器具受容スロット44内での前後の往復運動のためにガイド10の器具受容スロット44内に受容される。内側壁222の一部が、内側レール12の内壁54に近接して位置し、外側壁224の一部が外側レール14の内壁76に近接して位置する。後部カッター202の内側壁222と内側レール12の内壁54および後部カッター202の外側壁224と外側レール14の内壁76が協働して、後部カッター202が器具受容スロット44内に受容されている時のガイド10に対する後部カッター202の回転を制限する。

【0048】

後部カッター202の本体216の後端壁226および前端壁228が、変位244によって離間している。後端壁226と前端壁228との間のこの変位244は、ガイド10の器具受容スロット44の長さ48の半分未満である。例示されている実施形態では、後部カッター202は、ドライバ210によって駆動され、ガイド10の器具受容スロット44内を前後に往復運動するように構成されている。例示されているドライバ210は、後部カッター202を、器具受容スロット内を前後に約2mm往復運動させることができるように構成されている。従って、例示されている実施形態では、後端壁226と前端壁228との間の変位244は、ガイド10の器具受容スロット44の長さ48の半分未満の約2mmである。

【0049】

例えば図7に示されているように、後部カッター202の後端壁226は、後部戻しばね206の一部を受容できる大きさの孔246を含むように形成されている。孔246は、後部戻しばね206の直径250よりも大きい直径248を有する。孔246はまた、後部戻しばね206が内部に受容されて孔246の底壁254とガイド10の後側交差部材16との間で圧縮された時に、後部戻しばね206が孔246から外れない十分な深さ252を有する。後部戻しばね206は、後部カッター202がガイド10に対して後方に移動した時にガイド10内の中心位置まで後部カッター202を前方に戻すように構成されている。図示されていないが、ガイド10の後側交差部材16を、後部戻しばね206の他端を受容するための同様の孔を含むように構成することも本開示の範囲内である。

【0050】

例えば図7、および図6に破線で示されているように、後部カッター202の前端壁228は、後部カッター202の本体216内に後方に延びたキャビティ258を含むように形成されている。このキャビティ258は、ドライバ210のカム面262に係合する接触面260を含む。例示されている実施形態では、キャビティ258は、前端壁228と同一平面にあるその長軸264および前端壁228に垂直な半短軸266を有する半楕円キャビティである。長軸264は、ドライバ210の楕円カム270の長軸268よりも僅かに長く、半短軸266は、楕円カム270の短軸272の半分にほぼ等しい。

【0051】

キャビティ258は、ドライバ210の楕円カム270がキャビティ258内で回転で

きるようにその楕円カム270の厚み370よりも僅かに高い高さ274を有する。キャビティ258の接触面260およびドライバ210のカム面262は、ドライバ210がそのシャフト280の長軸278を中心に回転すると、楕円カム270の長軸268と短軸272との差に等しい距離、後部カッター202がガイド10内を前後に往復運動するように構成されている。

【0052】

半円柱溝282が、後部カッター202の上壁218とキャビティ258との間に延在する後部カッター202の前端壁228に形成されている。半円開口284が、キャビティ258と溝282の交差部分におけるキャビティ258の上壁218に形成されている。半円開口284はまた、上壁218と溝282の交差部分における後部カッター202の上壁218にも形成されている。半円柱溝282は、上壁218の接線に垂直、かつ内側壁222および外側壁224に平行に、前端壁228と同一平面上に軸286と同軸的に形成されている。後部カッター202および前部カッター204の両方がガイド10内の中心位置にくると、半円柱溝282が前部カッター204の同様の半円柱溝382と協働して、シャフト280の長軸278を中心に回転運動できるように内部にドライバ210のシャフト280を受容する。従って、半円溝282は、ドライバ210のシャフト280の直径290の半分よりも僅かに大きい半径288を有する。

【0053】

例示された実施形態では、前部カッター204は後部カッター202と対称である。切削器具200の第2の実施形態のカッター部品を減らすために、前部カッター204および後部カッター202として使用できるように、ガイド10内の両方向の向きに対して複数の単一カッターを製造することができる。

【0054】

前部カッター204は、上壁318、切削面320、内側壁322、外側壁324、後端壁326、および前端壁328を有する本体316を含む。内側壁322および外側壁324は、上壁318と切削面320の間および前端壁328と後端壁326の間に延在し、これらを結合している。

【0055】

例示されている実施形態では、上壁318および切削面320は、前部カッター204に一致する単一区画膝関節プロテーゼの大腿骨コンポーネントの内面の前後の曲率に一致する前後の曲率を有する。当業者であれば、上壁318の曲率は前部カッター204の動作にとって重要ではないが、カッター204に審美性および安全性を付与することを理解できよう。従って、上壁318が平坦であることや、上壁318が切削面320とは異なる曲率を有することも開示の範囲内である。

【0056】

切削面320は、その切削面320に亘って内側-外側に延在する複数列の歯330を含むように形成されている。切削面320およびその切削面320に形成されている複数の歯330は、内側-外側に亘って平坦にしても良いし、または前部カッター204に一致する単一区画膝関節プロテーゼの大腿骨コンポーネントの内側-外側の曲率に一致する凹状または凸状の内側-外側の曲率を有するようにしても良い。

【0057】

例示されている実施形態では、複数のガイドピン214は、前部カッター204の内側壁322から垂直に延びた内側前部ガイドピン332および内側後部ガイドピン334、並びに前部カッター204の外側壁324から垂直に延びた外側前部ガイドピン336および外側後部ガイドピン338を含む。複数のガイドピン214は、前部カッター204の切削面320の接線に平行な平面を画定している。例示的に、複数のガイドピン214はそれぞれ、湾曲スロット58、80の幅68、90よりも僅かに小さい直径240を有するため、ガイドピン214が、湾曲スロット58、80内に受容されると、湾曲スロット58、80内を前後に往復運動することができる。ガイドピン214は、前部カッター204の本体316の内外にその長軸に沿って往復運動できるようにばね付勢することが

できる。

【0058】

前部カッター204の本体316の内側壁322および外側壁324は、変位342によって平行に離間している。内側壁322と外側壁324との間のこの変位342は、ガイド10の器具受容スロット44の幅46よりも僅かに小さいがほぼ同じである。使用の際、前部カッター204の一部が、器具受容スロット44内の前後の往復運動のためにガイド10の器具受容スロット44内に受容される。内側壁322の一部が、内側レール12の内壁54に近接して位置し、外側壁324の一部が外側レール14の内壁76に近接して位置する。前部カッター204の内側壁322と内側レール12の内壁54および前部カッター204の外側壁324と外側レール14の内壁76が協働して、前部カッター204が器具受容スロット44内に受容されている時のガイド10に対する前部カッター204の回転を制限する。

【0059】

前部カッター204の本体316の後端壁326および前端壁328が、変位344によって離間している。後端壁326と前端壁328との間のこの変位344は、ガイド10の器具受容スロット44の長さ48の半分未満である。例示されている実施形態では、前部カッター204は、ドライバ210によって駆動され、ガイド10の器具受容スロット44内を前後に往復運動するように構成されている。例示されているドライバ210は、前部カッター204を、器具受容スロット44内を前後に約2mm往復運動させることができるように構成されている。従って、例示されている実施形態では、後端壁326と前端壁328との間の変位344は、ガイド10の器具受容スロット44の長さ48の半分未満の約2mmである。

【0060】

例えば図7に示されているように、前部カッター204の前端壁328は、前部戻しばね208の一部を受容できる大きさの孔346を含むように形成されている。孔346は、前部戻しばね208の直径350よりも大きい直径348を有する。孔346はまた、前部戻しばね208が内部に受容されて孔346の底壁354とガイド10の前側交差部材18との間で圧縮された時に、前部戻しばね208が孔346から外れない十分な深さ352を有する。前部戻しばね208は、前部カッター204がガイド10に対して前方に移動した時にガイド10内の中心位置まで前部カッター204を後方に戻すように構成されている。図示されていないが、ガイド10の前側交差部材18を、前部戻しばね208の他端を受容するための同様の孔を含むように構成することも本開示の範囲内である。

【0061】

例えば図7、および図6に破線で示されているように、前部カッター204の後端壁326は、前部カッター204の本体316内に前方に延びたキャビティ358を含むように形成されている。このキャビティ358は、ドライバ210のカム面262に係合する接触面360を含む。例示されている実施形態では、キャビティ358は、後端壁326と同一平面にあるその長軸364および後端壁326に垂直な半短軸366を有する半楕円キャビティである。長軸364は、ドライバ210の楕円カム270の長軸268よりも僅かに長く、半短軸366は、楕円カム270の短軸272の半分にはほぼ等しい。

【0062】

キャビティ358は、ドライバ210の楕円カム270がキャビティ358内で回転できるようにその楕円カム270の厚み370よりも僅かに高い高さ374を有する。キャビティ358の接触面360およびドライバ210のカム面262は、ドライバ210がそのシャフト280の長軸278を中心に回転すると、楕円カム270の長軸268と短軸272との差に等しい距離、前部カッター204がガイド10内を前後に往復運動するように構成されている。

【0063】

半円柱溝282が、前部カッター204の上壁318とキャビティ358との間に延在する前部カッター204の後端壁326に形成されている。半円開口384が、キャビテ

ィ358と溝382の交差部分におけるキャビティ358の上壁318に形成されている。半円開口384はまた、上壁318と溝382の交差部分における前部カッター204の上壁318にも形成されている。半円柱溝382は、上壁318の接線に垂直、かつ内側壁322および外側壁324に平行に、後端壁326と同一平面上に軸386と同軸的に形成されている。後部カッター202および前部カッター204の両方がガイド10内の中心位置にくると、半円柱溝382が後部カッター202の同様の半円柱溝282と協働して、シャフト280の長軸278を中心に回転運動できるように内部にドライブ210のシャフト280を受容する。従って、半円溝382は、ドライブ210のシャフト280の直径290の半分よりも僅かに大きい半径388を有する。

【0064】

ドライブ210は、楕円カム270およびシャフト280を含む。例示的に、シャフト280は、長軸278を中心に同軸的に形成され、駆動源114の駆動軸112に結合するように構成されている。楕円カム270は、上壁294と底壁296との間に延在し、これらを結合するカム面262を含む。上壁294は、楕円カム270の厚み370によって底壁296から変位している。カム面262は、長軸268および短軸272を有する。ドライブ210のシャフト280は、楕円カム270の主軸268と短軸272の交差部分から垂直にシャフト280の長軸278が延在するように楕円カム270の上壁294に結合されている。長軸268の長さは、短軸272の長さよりも長い。例示されている実施形態では、長軸268は短軸272よりも約4mm長い。従って、ドライブ210がそのシャフト280の長軸278を中心に回転すると、楕円カム270のカム面262がキャビティ258、358の接触面260、360に係合し、後部カッター202および前部カッター204の両方がガイド10内で前後に約2mm移動する。

【0065】

例示されていないが、切削器具200の第2の実施形態は、回転中のドライブ210のシャフト280の整合を維持するためにガイド10に取り付けできるように構成された整合カラーを含むこともできる。このような整合カラーは、シャフト受容孔および複数のピンホールを含むように形成された本体を含むことができる。ピンホールは、ガイド10の内側中心耳26および外側中心耳32に形成されたねじ受容孔29をねじ31が貫通するように本体に形成することができる。整合カラーの底壁は、カラーに安定性を与えるために外側レール14および内側レール12の上壁に連続的に係合するように構成することができる。シャフト受容孔は、長軸を中心に同軸的に形成された円筒側壁によって画定することができる。整合カラーの円筒側壁は、内部にドライブ210のシャフト280を受容するように構成され、ドライブ210のシャフト280がその長軸278を中心に内部で自由に回転できる大きさを有する。整合カラーの円筒側壁は、ガイド10と協働して、ドライブ210のシャフト280の整合および中心位置を維持することができる。従って、整合カラーのシャフト受容孔の内径は、ドライブ210の不整合を制限するためにドライブ210のシャフト280の外径よりも僅かに大きくすることができる。

【0066】

例示されているように、ガイドピン214は、湾曲スロット58、80の凸状底壁62、84の曲率に一致する曲率を有する経路に後部カッター202および前部カッター204を従わせるように構成されたトラックフォロアとして機能する。当業者であれば、限定するものではないが、後部カッター202および前部カッター204のそれぞれの本体216、316から延びた壁部、ボス、耳、およびフランジを含み、湾曲スロット58、80内での前後の往復運動の際に湾曲スロット58、80によって受容され案内されるように構成された他のトラック追従装置を開示の範囲内で用いることができることを理解できるように。また、内側レールおよび外側レールを湾曲底壁および湾曲上壁で形成してトラックとして機能させること、および後部カッター202および前部カッター204が、本体216、316から延びたガイドピン、壁部、ボス、耳、およびフランジなどのトラックフォロアを含み、トラックとして機能する湾曲底壁および湾曲上壁に従うように構成することも開示の範囲内である。

【0067】

使用の際は、ガイドピン214は、ガイド10の湾曲スロット58、80内に保持されると、湾曲ガイド面すなわちトラックを画定する湾曲スロット58、80の凸状底壁62、84に接触する。湾曲スロット58、80の凹状上壁60、82は、ガイドピン214のガイド10に対する近位側および遠位側の動きを制限する働きをする。ガイドピン214は、湾曲スロット58、80内に受容され、後部カッター202および前部カッター204の切削面220、320のそれぞれが特定のガイド10およびカッター202、204に関連した単一区画関節プロテーゼの大腿骨コンポーネントの内面の曲率に近い曲率に沿って移動するように制限する働きをする。

【0068】

ガイド1210の第2の実施形態および切削器具1300の第3の実施形態を含む骨整形器具の代替の実施形態が、例えば図12に示されている。ガイド1210の第2の実施形態は、ガイド10の第1の実施形態に極めて類似しているため、同一の構成要素には同一の参照番号を用い、類似の構成要素には類似の参照番号を用いた。ガイド10と同様に、ガイド1210は、器具受容スロット内を前後方向に延在する平面を中心に対称に形成されている。従って、図12はガイド1210の外側からの側面図であるため外側の構成要素のみを説明および参照番号を付したが、内側の構成要素も同様に設けられていることを理解されたい。ガイド1210は、内側レール、外側レール1214、後側交差部材16、前側交差部材18、後脚19、前脚21、および複数の耳1230、1232、および1234を含む。後側交差部材16は、内側レールの後端部と外側レール1214の後端部との間に延在し、これらを結合している。前側交差部材18が、内側レールの前端部と外側レール1214の前端部との間に延在し、これらを結合している。内側レール、外側レール1214、後側交差部材16、および前側交差部材18が協働して、器具受容スロットを画定している。切削器具1300の一部が器具受容スロットを介して延在し、かつ/または駆動源の駆動シャフトが切削器具1300を駆動するためにこの器具受容スロットを介して切削器具1300まで延びている。

【0069】

例示されている実施形態では、内側レールと外側レール1214が互いに長手方向に平行に延在し、器具受容スロットの側壁を画定している。内側レールと外側レール1214は、器具受容スロットの幅を画定する変位によって互いに離間している。一実施形態では、器具受容スロットの幅は、低侵襲性処置で使用し易いように約13mmである。

【0070】

後側交差部材16および前側交差部材18は、互いに横方向に平行に延在し、器具受容スロットの端壁を画定している。後側交差部材16と前側交差部材18は、器具受容スロットの長さを画定する変位によって互いに離間している。

【0071】

外側レール1214は、凹状底壁1272、凸状上壁1274、内壁、および外壁1278を含む。内壁および外壁1278は、互いに概ね平行であって、凹状底壁1272と凸状上壁1274との間に延在し、これらを結合している。凹状底壁1272および凸状上壁1274はそれぞれ、特定のガイド1210に関連した単一区画関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0072】

外側レール1214は、外壁1278から外側に延びた外側後部耳1230、外側中心耳1232、および外側前部耳1234を含むように形成されている。外側後部耳1230は、外側レール1214の後端部1238に近接して位置する。外側前部耳1234は、外側レール1214の前端部1242に近接して位置する。外側中心耳1232は、外側後部耳1230と外側前部耳1232の間の外側レール1214の中心付近に位置する。外側後部耳1230、外側中心耳1232、および外側前部耳1234はそれぞれ、ガイド1210を大腿骨に固定するためにねじ31を受容するように構成されたねじ受容孔を含むように形成されている。ねじ受容孔は、特定のガイド1210に関連した単一区画

膝関節プロテーゼの大腿骨コンポーネントの下側の曲率の中心の焦点に向かって径方向に延びた軸を中心に同軸的に形成されている。ねじ受容孔の向きにより、ガイド1210を大腿骨に固定するために低侵襲性切開部を介してねじ31を挿入するのが容易である。

【0073】

切削器具1300の第3の実施形態は、切削器具100の第1の実施形態に極めて類似しているため、同一の構成要素には同一の参照番号を用い、類似の構成要素には類似の参照番号を用いた。誘導切削器具1300の第3の実施形態は、深さストッパー102、カッター104、および保持カラー1310を含む。切削器具1300の保持カラー1310のみが切削器具100の構成要素と異なっているため、保持カラー1310のみを詳細に説明するが、誘導切削器具100の深さストッパー102およびカッター104の説明を誘導切削器具1300の深さストッパー102およびカッター104に適用できることを理解されたい。

【0074】

保持カラー1310は、シャフト受容孔および複数のガイドピン1320を含むように形成された本体1316を含む。保持カラー1310の本体1316は、上壁1326と底壁1328の間および前壁1330と後壁1332の間に延在し、これらを結合する平行に離間した側壁を含む。上壁1326は、平面であって、深さストッパー102に係合してカッター104の切削深さを制限するストッパー面として機能するように構成されている。シャフト受容孔は、上壁1326および底壁1328を貫通している。例示的に、シャフト受容孔は、上壁1326に垂直な長軸1336を中心に同軸的に形成された円筒側壁によって画定されている。円筒側壁は内径を有する。例示的に、円筒側壁は、その内部にカッター104のシャフト108を受容するように構成され、カッター104のシャフト108がその長軸140を中心に内部に自由に回転できる大きさを有する。円筒側壁は、カッター104のシャフト108と協働し、保持カラー1310と深さストッパー102により、カッター104の整合が維持される。従って、シャフト受容孔の内径は、カッター104の不整合を制限するためにカッター104のシャフト108の外径よりも僅かに大きい。例示されている実施形態では、カッター104のシャフト108は、低侵襲性切開部を介して骨整形器具を使用し易いように径方向に延在するように整合されている。

【0075】

例示されている実施形態では、複数のガイドピン1320は、保持カラー1310の内側壁から垂直に延びた内側前上部ガイドピン、内側前下部ガイドピン、内側後上部ガイドピン、内側後下部ガイドピン、並びに保持カラー1310の外側壁1324から垂直に延びた外側前上部ガイドピン1348、外側前下部ガイドピン1349、外側後上部ガイドピン1350、および外側後下部ガイドピン1351を含む。ガイドピン1320は、保持カラー1310の上壁1326に平行な平面を画定している。例示的に、保持カラー1310が器具受容スロット内を前後に往復運動する場合、内側前上部ガイドピンおよび内側後上部ガイドピンが内側レールの凸状上壁1274上を摺動し、内側前下部ガイドピンおよび内側後下部ガイドピンが内側レールの凹状下部壁1272に対して摺動する。保持カラー1310が器具受容スロット内を前後に往復運動する場合、外側前上部ガイドピン1348および外側後上部ガイドピン1350が外側レール1214の凸状上壁1274上を摺動し、外側前下部ガイドピン1349および外側後下部ガイドピン1351が外側レール1214の凹状底壁1272に対して摺動する。ガイドピン1320は、保持カラー1310の本体1316の内外にそれらの長軸に沿って往復運動できるようにばね付勢することができる。

【0076】

保持カラー1310の本体1316の内側壁および外側壁1324は、ガイド1210の器具受容スロットの幅よりも僅かに小さいがほぼ同じ大きさの変位によって離間している。使用の際は、保持カラー1310の一部が、器具受容スロット内での前後の往復運動のためにガイド1210の器具受容スロット内に受容される。内側壁の一部が、内側レー

ルの内壁に近接して位置し、外側壁1324の一部が外側レール1214の内壁に近接して位置する。

【0077】

例示的に、ガイドピン1320は、トラックフォロアとして機能して、内側レールの凹状底壁および凸状上壁および外側レール1214の凹状底壁1272および凸状上壁1274の曲率に一致する曲率を有する経路に保持カラー1310を従わせるように構成されている。当業者であれば、限定するものではないが、保持カラー1310の本体1316から延びた壁部、ボス、耳、およびフランジを含み、内側レールの凹状底壁および凸状上壁、並びに外側レール1214の凹状底壁1272および凸状上壁1274に係合して案内されるように構成された他のトラック追従装置を開示の範囲内で利用できることを理解できよう。

【0078】

ガイド1410の第3の実施形態および切削器具1500の第4の実施形態を含む骨整形器具のさらに別の代替の実施形態が、例えば図13および図14に示されている。ガイド1410は、ガイドプレート1412、前部ピン受容シリンダ1428、および後部ピン受容シリンダ1424を含む。

【0079】

例示的に、ガイドプレート1412は、凹状底壁1450、凸状上壁1452、内壁1454、および外壁1456を含む。内壁1454および外壁1456はそれぞれ、平坦であって、互いに概ね平行である。内壁1454および外壁1456は、凹状底壁1450と凸状上壁1452との間に延在し、これらを結合している。凹状底壁1450および凸状上壁1452はそれぞれ、特定のガイド1410に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0080】

ガイドプレート1412は、内壁1454と外壁1456との間にそれぞれ延在する凹状上壁1460、凸状底壁1462、後壁1464、および前壁1466によって画定された湾曲スロット1458を含むように形成されている。凹状上壁1460および凸状底壁1462はそれぞれ、特定のガイド1410に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致した曲率を有する。

【0081】

凹状上壁1460と凸状底壁1462は、湾曲スロット1458の幅である変位によって互いに離間している。湾曲スロット1458の幅は、湾曲スロット1458内での前後の長手方向の運動のために内部にガイドピン1520を受容できる大きさである。湾曲スロット1458の前壁1466および後壁1464は、湾曲スロット1458の長さである変位によって互いに離間している。前壁1466および後壁1464は、ガイドピン1520が湾曲スロット1458内に受容された時にガイドピン1520の前後の長手方向の運動を制限するストッパーとして機能する。

【0082】

ガイドプレート1412は、後部ピン受容シリンダ1424および前部ピン受容シリンダ1428を含むように形成されている。後部ピン受容シリンダ1424は、ガイドプレート1412の後端部1436に結合されている。前部ピン受容シリンダ1428は、ガイドプレート1412の前端部1440に結合されている。前部ピン受容シリンダ1428および後部ピン受容シリンダ1424はそれぞれ、ガイド1410を大腿骨に固定するためにねじ31を受容するように構成されたねじ受容孔1429を含むように形成されている。ねじ受容孔1429は、特定のガイド1410に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率の中心の焦点に向かって径方向に延びた軸を中心に同軸的に形成されている。ねじ受容孔1429の向きにより、ガイド1410を大腿骨に固定するために低侵襲性切開部を介してねじ31を挿入するのが容易である。

【0083】

切削器具1500の第4の実施形態は、切削器具100の第1の実施形態に極めて類似

しているため、同一の構成要素には同一の参照番号を用い、類似の構成要素には類似の参照番号を用いた。誘導切削器具1500の第4の実施形態は、カッター104および保持カラー1510を含む。図示されていないが、当業者であれば、誘導切削器具1500が深さストッパー102も含むことができることを理解できよう。切削器具1500の保持カラー1510のみが切削器具100の構成要素と異なっているため、保持カラー1510のみを詳細に説明するが、誘導切削器具100の深さストッパー102およびカッター104の説明を誘導切削器具1500の深さストッパー102およびカッター104に適用できることを理解されたい。

【0084】

保持カラー1510は、複数のガイドピン1520の1つを受容するようにそれぞれ構成された複数のガイドピンねじ孔1517およびシャフト受容孔を含むように形成された本体1516を含む。保持カラー1510の本体1516は、上壁1526と底壁1528の間および前壁1530と後壁1532の間に延在し、これらを結合する平行に離間した側壁を含む。上壁1526は、平面であって、深さストッパー102が係合してカッター104の切削深さを制限するストッパー面として機能するように構成されている。シャフト受容孔は、上壁1526および底壁1528を貫通している。例示的に、シャフト受容孔は、上壁1526に垂直な長軸を中心に同軸的に形成された円筒側壁によって画定されている。円筒側壁は内径を有する。例示的に、円筒側壁は、内部にカッター104のシャフト108を受容するように構成され、カッター104のシャフト108がその長手軸140を中心に内部で自由に回転できる大きさを有する。円筒側壁がカッター104のシャフト108と協働し、保持カラー1510および深さストッパー102により、カッター104の整合が維持される。従って、シャフト受容孔の内径は、カッター104の不整合を制限するようにカッター104のシャフト108の外径よりも僅かに大きい。例示されている実施形態では、カッター104のシャフト108は、低侵襲性切開部を介して骨整形器具を利用し易いように径方向に延在するように整合している。

【0085】

例示されている実施形態では、複数のガイドねじピン1520は、前部ガイドピン1548および後部ガイドピン1550を含む。それぞれのガイドピン1520は、頭部1549、および本体1516のガイドピン受容孔1517に受容されるように構成されたねじシャフト1551を含む。従って、受容されると、ガイドピン1520が、保持カラー1510の外側の側壁1524から垂直に延出する。ガイドピン1520は、保持カラー1510の上壁1526に平行な平面を画定している。ガイドピン1520がガイドスロット1458を貫通して保持カラー1510の本体1516がガイド1410に結合されると、ガイドピン1520の頭部1549の内壁が、ガイド1410の外壁1456と近接または係合する。このようにガイド1410に結合すると、本体1516の外壁1524がガイド1410の内壁1454に近接または係合する。例示的に、保持カラー1510が前後に往復運動する場合、前部ガイドピン1548および後部ガイドピン1550が、ガイドスロット1458の凸状底壁1462上を摺動し、ガイドスロット1458の凹状上壁1460に対して摺動する。従って、ガイドピン1520の頭部1549の内壁とガイド1410の外壁1456、保持カラー1510の本体1516の外壁1524とガイド1410の内壁1454、ガイドピン1520のシャフト1551とガイドスロット1458の凸状底壁1462および凹状上壁1460が協働して、骨の切削の間、切削器具104の適切な整合を維持する。

【0086】

例示的に、ガイドピン1520は、トラックフォロアとして機能して、ガイドスロット1458の凹状上壁1460および凸状底壁1462の曲率に一致する曲率を有する経路に保持カラー1510を従わせるように構成されている。当業者であれば、限定するものではないが、保持カラー1510の本体1516から延びた壁部、ボス、耳、およびフランジを含み、ガイドスロット1458の凹状上壁1460および凸状底壁1462に係合して案内されるように構成された他のトラック追従装置も開示の範囲内であることを理解

できよう。

【0087】

ガイド1610の第3の実施形態および切削器具1700の第4の実施形態を含む骨整形器具のさらに別の代替の実施形態が、例えば図15-図17に示されている。

【0088】

ガイド1610は、ガイドプレート1612を含み、ガイド1410に極めて類似しているが、ピン受容シリンダ1424および1428を含まない点がことなる。ガイド1610は、骨の所望の位置に形成された切除スロット1611内にガイド1610を挿入して切削する骨に取り付けられる。

【0089】

例示的に、ガイドプレート1612は、凹状底壁1650、凸状上壁1652、内壁1654、および外壁1656を含む。内壁1654と外壁1656はそれぞれ、平坦であって、互いに概ね平行である。内壁1654および外壁1656は、凹状底壁1650と凸状上壁1652との間に延在し、これらを結合している。凹状底壁1650および凸状上壁1652はそれぞれ、特定のガイド1610に関連した単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0090】

ガイドプレート1612は、内壁1654と外壁1656の間にそれぞれ延在する凹状上壁1660、凸状底壁1662、後壁1664、および前壁1666によって画定された湾曲スロット1658を含むように形成されている。凹状上壁1660および凸状底壁1662はそれぞれ、特定のガイド1610の単一区画膝関節プロテーゼの大腿骨コンポーネントの下側の曲率に一致する曲率を有する。

【0091】

凹状上壁1660および凸状底壁1662は、湾曲スロット1658の幅である変位によって互いに離間している。湾曲スロット1658の幅は、その湾曲スロット1658内での前後の長手方向の運動のために内部にガイドブシュ1720の中心シャフト1751を保持できる大きさである。湾曲スロット1658の前壁1666および後壁1664は、湾曲スロット1658の長さである変位によって互いに離間している。前壁1666および後壁1664は、ガイドブシュ1720が湾曲スロット1658内に保持された時にその前後の長手方向の運動を制限するストッパーとして機能する。

【0092】

切削器具1700の第5の実施形態は、切削器具100の第1の実施形態に極めて類似しているため、同一の構成要素には同一の参照番号を用いて、類似の構成要素には類似の参照番号を用いた。誘導切削器具1700の第5の実施形態は、カッター1704および保持カラー1710を含む。カッター1704は、カッター104に極めて類似しているが、基端部1709に近接した大径部分1707および先端部1713に近接した小径部分1711を含むように形成された駆動シャフト1708、およびシャフト1708の先端部1713に取り外し可能に取り付けできるように構成された切削面1706を含むモジュラーである点が異なっている。シャフト1708の直径の大きい部分1707の先端壁1715が深さストッパーとして機能する。切削面1706は、保持カラー1710をシャフト1708の直径の小さい部分1711に取り付け易く、かつ切削面1706を交換し易いように、シャフト1708に取り外し可能に取り付けられている。

【0093】

保持カラー1710は、カップリング1782のシャフト受容孔および雄部分1780を含むように形成された本体1716、カップリング1782の雌部分1786を含むように形成された本体プレート1784、複数のモジュラーガイドブシュ1720、外側プレート1788、および複数のねじ1790を含む。

【0094】

シャフト1708の小径部分1711を、本体1716のシャフト受容孔内に装入して、保持カラー1710をカッター1704に結合する。本体1716は、上壁1726と

底壁1728の間に延在し、これらを結合する円筒側壁1724を含む。上壁1726は、平面であって、シャフト1708の大径部分1707の先端壁1715に係合してカッター1704の切削深さを制限するストッパー面として機能するように構成されている。シャフト受容孔は、上壁1726および底壁1728を貫通している。例示的に、シャフト受容孔は、上壁1726に垂直な長軸を中心に同軸的に形成された円筒側壁によって画定されている。円筒側壁は内径を有する。例示的に、円筒側壁は、内部にカッター1704のシャフト1708の小径部分1711を受容するように構成され、カッター1704のシャフト1708の小径部分1711が長軸1740を中心に内部で自由に回転できる大きさを有する。円筒側壁は、カッター1704のシャフト1708の小径部分1711と協働してカッター1704の整合を維持する。従って、シャフト受容孔の内径は、カッター1704の整合のずれを制限するためにカッター1704のシャフト1708の小径部分1711の外径よりも僅かに大きい。

【0095】

例示された実施形態では、複数のモジュラーガイドブシュ1720が、モジュラー前部ガイドブシュ1748およびモジュラー後部ガイドブシュ1750を含む。モジュラーガイドブシュ1720はそれぞれ、頭部1749およびシャフト1751を有する第1の部分1747、およびキャップ1755を有する第2の部分1753を含む。シャフト1751は、ガイド1610のガイドスロット1658内に受容されるように構成されている。

【0096】

本体1716のカップリング1782の雄部分1780を本体プレート1784のカップリング1782の雌部分1786に結合させて、本体1716を本体プレート1784に結合する。例示された実施形態では、カップリング1782の雄部分1780は、本体1716の円筒壁1724から径方向に延びたT型突出部であり、カップリング1782の雌部分1786は、本体プレート1784に水平に形成されたスロットである。T型突出部をスロット内に挿入して本体プレートを90度回転させ、本体1716を本体プレート1784に結合する。保持カラー1710を完全に組み立てると、キャップ1755がT型突出部に係合し、本体1716の本体プレート1784に対する回転が防止される。本体1716の本体プレート1784への結合に用いられる他の一般的な結合形態も開示の範囲内である。

【0097】

本体1716を本体プレート1784に取り付けた後、モジュラーガイドブシュ1720のシャフト1751をガイドプレート1610のガイドスロット1658内に挿入し、保持カラー1710を組み立てる。モジュラーガイドブシュ1720のキャップ1755をモジュラーガイドブシュ1720のシャフト1751に取り付け、ねじ1790を、外側プレート1788、モジュラーブシュ1720、および本体プレート1784の中を通して保持カラー1710を完全に組み立てる。例示された実施形態では、保持カラー1710の組立てを容易にするために、ねじ孔が、外側プレート1788、モジュラーブシュ1720、および本体プレート1784に設けられている。

【0098】

このように組み立てると、ガイドブシュ1720が、保持カラー1710の本体1716の長軸に垂直に延在する。ガイドブシュ1720は、保持カラー1710の上壁1726に平行な平面を画定している。ガイドブシュ1720のシャフト1751をガイドスロット1658内に通して保持カラー1710をガイド1610に結合すると、ガイドブシュ1720の頭部1749の内壁がガイド1610の外壁1656に近接または係合する。ガイド1610がこのように結合すると、ガイドブシュ1720のキャップ1755の外壁がガイド1610の内壁1654に近接または係合する。例示的に、前部ガイドブシュ1748および後部ガイドブシュ1750の各シャフト1751が、保持カラー1710が前後に往復運動する時にガイドスロット1658の凸状底壁1662上を摺動し、ガイドスロット1658の凹状上壁1666に対して摺動する。従って、ガイドブシュ17

20の頭部1749の内壁とガイド1610の外壁1656、保持カラー1710のガイドブシュ1720のキャップ1755の外壁とガイド1610の内壁1654、並びにガイドブシュ1720のシャフト1751とガイドスロット1658の凸状底壁1662および凹状上壁1660が協働して、骨の切削の際に切削器具1704の適切な整合を維持する。

【0099】

例示的に、ガイドブシュ1720は、トラックフォロアとして機能し、ガイドスロット1658の凹状上壁1660および凸状底壁1662の曲率に一致する曲率を有する経路に保持カラー1710を従わせるように構成されている。当業者であれば、限定するものではないが、保持カラー1710の本体1716から延びた壁部、ボス、耳、およびフランジを含み、ガイドスロット1658の凹状上壁1660および凸状底壁1662に係合して案内されるように構成された他のトラック追従装置も本開示の範囲内で用いることができることを理解できよう。

【0100】

開示した骨整形器具を利用するのに適した単一区画膝関節置換術の一実施形態では、まず外科医が、前内側または前外側の皮膚切開を行う。この切開は、膝蓋骨の上縁の近位側1cmから始めるべきである。膝蓋骨および膝蓋骨腱の縁に沿って遠位側に6cm〜10cm延ばし、関節線の遠位側2cmで止める。このような処置を初めて行う場合または患者が肥満の場合は、切開部を長くするのが望ましいであろう。

【0101】

次いで外科医が、膝蓋骨側切開部から関節包にアクセスする。関節が露出したら、関節炎の損傷の程度およびこの処置に関節が適しているかを最終的に評価することができる。外科医は、内側または外側の関節包の深い半月板-脛骨層を反転して全ての脛骨骨棘にアクセスし易くし、正確に創傷を閉じることができるようにする。外科医はまた、全ての過剰な深い滑膜を切除し、関節を見易くする。必要に応じて、脂肪パッドの全てまたは一部を切除して、見易くし、反対側の区画を検査し易くする。

【0102】

この外科処置での全ての段階での関節へのアクセスを維持するためにレトラクタを挿入することができる。靱帯を緩める必要はない。内側/外側(M/L)整合および関節の安定性を達成するために、大腿骨および脛骨の内側または外側の全ての縁から全ての骨棘を除去するべきである。レトラクタを膝蓋骨の縁に配置して、膝蓋骨を中心位置に合わせることができる。

【0103】

次いで、外科医が人工関節片側置換術(UKR)の脛骨切除を行う。脛骨切除を行うために、膝を90度折り曲げる。デピュイ(DePuy)が販売する保存的脛骨切除ブロック(Preservation Tibial Cutting Block, Cat.No.2498-60-002,004)などの脛骨整合ガイドをこの脛骨切除に用いることができる。このような整合ガイドの脛骨切除ブロックは、関節線のすぐ下側まで上げるべきである。

【0104】

内側UKRを行う場合、脛骨切除ブロックを脛骨結節の中心から内側に約2mmの位置に配置する。M/L調節は、脛骨の機械的な軸に対して垂直な内反/外反整合を達成するために近位側で行う。次いで、脛骨の前後の傾斜を、基準として脛骨の前頭稜を用いて設定する。後側の脛骨の傾斜は、約3度〜5度、または側方X線を用いた手術前の型取りから決定された外形に調節する。

【0105】

次いで、上下および前後の傾斜を固定する。次いで外科医が、基準点として人体構造の目印を用いて往復鋸でL型に切除する。内側単一区画の場合は、内側大腿骨顆の外側の縁に対してすぐ外側にL型に切除すべきである。L型の切除は、目印としてACLの挿入の外側の縁の中間点を用いて矢状面に整合させる。

【0106】

次いで外科医が、振動鋸に取り付けた鋸歯を用いて適切な向きに脛骨を横方向に切除する。切除した脛骨の細片を除去する。

【0107】

初めの遠位大腿骨切開部を用いて或いは用いずに、大腿骨の内側顆の切除を行うことができる。初めの遠位大腿骨切開部を用いる場合、PRESERVATION（商標）システムの整合ガイドを推奨される使用方法に従って用いることができる。脚を完全に延ばした状態に維持し、整合ガイドおよび髄外整合ロッドを遠位大腿骨切除ブロックのスロット内に入れて全体の整合をチェックする。内反／外反整合を前面で評価することができる。遠位大腿骨切除の中立位置を側方から確認することができる。振動鋸を用いて遠位大腿骨切除を行うことができる。遠位大腿骨から除去する骨は最小限である。切除した遠位の骨を除去したら、残っている全ての軟組織を半月板の縁および後側の脛骨から取り除く。

【0108】

初めの遠位大腿骨切開部を利用することにより、既知の方法で大腿骨の回動およびサイジングガイドを用いて手術前の型取りの際に決定された大腿骨の大きさを決定することができる。ガイドの前端の形状およびM／L幅は、大腿骨プロテーゼと同じである。これは、滑車から大腿骨プロテーゼの前端への膝蓋骨の移行をスムーズにするため、およびインプラントのオーバーハングを回避するためである。大腿骨コンポーネントは、膝蓋骨と大腿骨の接合部を越えることなく遠位大腿骨軟骨の侵食をカバーするように選択する。サイズとサイズの中間の場合は、通常は小さい方を選択する。

【0109】

大腿骨の前側の回動を容易にするには、脛骨プラドーに対する大腿骨の中心M／L関節運動点を示す長手方向の印を完全に延びた状態で大腿骨顆に付ける。ガイドの前端をこの印に合わせて、正確な大腿骨の整合を確認することができる。大腿骨コンポーネントが大腿骨の前側を越えないようにすることも重要である。適切な大腿骨コンポーネントを選択したら、選択したコンポーネントに一致する誘導切削器具100、200およびガイド10を大腿骨に取り付ける前に組み立てる。

【0110】

次のステップを用いてガイドを大腿骨コンポーネントに配置し整合する。(1)膝を曲げた状態で、前側フットが前顆の支持部分の基端側にくるようにガイドを配置する。(2)ガイド10を、大腿骨を最大限にカバーできるように適切な内側-外側および回転位置(遠位側支持面に沿って)に配置する。ガイド10のトラックは、大腿骨インプラントの外側の内側-外側形状と同じである。(3)大腿骨の整合のためにガイドを適切に回転させる。大腿骨インプラントの遠位面と後面との間の解剖学的な角度を、大腿骨の解剖学的な形状を正確に再現する7度にする。(4)ガイド10の中心における接線が大腿骨の長軸に垂直になるようにしてガイド10の適切な内反／外反の位置を決定する。

【0111】

別法では、CAS法を用いることができる場合、この方法を用いて、記録した骨の形状に基づいてガイドを正確に配置することができる。当業者であれば、CASシステムを用いる場合の記録方法は周知である。

【0112】

ガイド10が正確に配置されたら、ガイド10を、例えば図8-図11に示されているように外側前部耳および内側後部耳の両方の孔29に0.125インチ(約3.2mm)の頭部のない固定ピンを通して固定する。追加のピンをガイド10の内側中心耳の孔29に配置して、後顆の切除の際に安定性が維持されるようにする。硬い骨すなわち強膜骨の場合、0.125インチ(約3.2mm)の迅速切断ドリルビットを用いて予め孔を穿孔する必要があるであろう。追加のピンを、空いているガイドの孔29に配置してさらに安定させることができる。カッターを用いる前に、高速バーで強膜骨の硬質層を除去する必要があるであろう。

【0113】

チップングやガウジングを避けるために、エンドミルを骨の中に導入する前に動力源を

起動すべきである。骨に係合したら、ガイドの長さに亘ってエンドミルを3回から4回骨の中に導入する。次いで、エンドミルをかき出し動作に用いて、残っている骨を除去する（エンドミルの切刃は側刃および底刃の両方である）。エンドミルが適切な深さに到達すると、深さストッパー102が保持カラーに接触してその前進が自動的に停止される。

【0114】

深さストッパーが行程の全経路に沿って移動して保持カラーに接触すると、適切な水準の準備が完了する。インプラントが適切に適合するように、これが行程の全経路に沿って完全に行われるのが重要である。

【0115】

最後の準備工程で、ベッグ形状またはギール形状などの任意の必要な構造を付加することができる。同じガイドレールを用いて、ドリルやバーなどの必要な準備器具を案内することができる。

【0116】

本発明の特定の実施形態をここに記載したが、当業者であれば、添付の特許請求の範囲によって規定される本発明の範囲から逸脱することなく他の実施形態にも想到するであろう。例えば、膝プロテーゼの大腿骨部分の移植に対して本発明を説明してきたが、肩、股関節、または肘などの他の関節のプロテーゼにも用いることができる。

【0117】

〔実施の態様〕 本発明の実施態様は以下の通りである。

(1) 曲率を有する表面に沿って骨の端部を切除するための骨切除器具であって、前記骨の端部に対して取り外し可能に固定位置に取り付けでき、かつ前記骨の切除する表面の曲率に概ね一致する曲率を有するトラックを含むように構成された、ガイドと、切削面を有する切削器具と、

前記切削器具に結合するように構成され、かつ前記トラックと協働して前記ガイドに対する前記切削器具の往復運動を容易にし、前記切削面が前記曲率を有する上面に沿って骨を切削するように構成されたトラックフォロアと、を含む、骨切除器具。

(2) 実施態様(1)に記載の骨切除器具であって、

前記切削器具に結合されたシャフトをさらに含み、このシャフトが、前記切削器具と協働して前記切削面が骨を切削するように構成されている、骨切除器具。

(3) 実施態様(2)に記載の骨切除器具であって、

前記シャフト、前記切削器具、前記トラックフォロア、および前記ガイドが、協働して前記曲率を有する表面に対して概ね垂直に前記シャフトを維持する、骨切除器具。

(4) 実施態様(3)に記載の骨切除器具であって、

前記シャフトに結合して前記シャフトをその長軸を中心に回転させるドライバをさらに含む、骨切除器具。

(5) 実施態様(4)に記載の骨切除器具であって、

前記シャフトは、前記切削面に固着されている、骨切除器具。

【0118】

(6) 実施態様(5)に記載の骨切除器具であって、

前記トラックフォロアおよび前記トラックは、前記切削器具が前記ガイドに対して前記トラックに沿って往復運動し易くするように構成されている、骨切除器具。

(7) 実施態様(6)に記載の骨切除器具であって、

前記切削面は、その端部および側面で切削するように構成されている、骨切除器具。

(8) 実施態様(5)に記載の骨切除器具であって、

前記ガイドは、前記曲率を有する表面に沿ってその上に延在する離間したレールを含み、

前記レールは、前記トラックを画定するよう協働する、骨切除器具。

(9) 実施態様(8)に記載の骨切除器具であって、

湾曲スロットが前記各レールを通るように形成され、前記湾曲スロットが協働して前記トラックを画定している、骨切除器具。

(10) 実施態様(8)に記載の骨切除器具であって、
前記シャフトの一部が前記離間したレール間に配置されている、骨切除器具。

【0119】

(11) 実施態様(9)に記載の骨切除器具であって、
前記シャフトの一部が前記離間したレール間に配置されている、骨切除器具。

(12) 実施態様(11)に記載の骨切除器具であって、
前記シャフトが、前記湾曲スロットの接線に垂直な前記シャフトの長軸に沿って往復運動するように構成されている、骨切除器具。

(13) 実施態様(12)に記載の骨切除器具であって、
前記シャフトにストッパーが形成されており、このストッパーが、前記トラックフォロアと協働して前記シャフトの骨に向かう往復運動を制限する、骨切除器具。

(14) 実施態様(13)に記載の骨切除器具であって、
前記ストッパーが、前記シャフトに対して長手方向に調節できるように構成されている、骨切除器具。

(15) プロテーゼコンポーネントの下側の曲面の曲率に一致する曲面に沿って骨を切除する方法であって、

切削する骨の表面を覆う組織を、低侵襲性式に切開するステップと、
前記プロテーゼコンポーネントの下側の曲面の曲率に一致するように構成されたトラックを含むガイドを、切除する骨の表面に沿って配置するステップと、
前記ガイドを前記骨に固定するステップと、
切削面を有するカッターを前記ガイドに相互連結するステップと、
前記切削面を、前記曲面の接線に概ね平行に維持するステップと、
前記カッターを前記トラックに沿って案内し、前記切削面を前記骨に沿って横断させるステップと、を含む、方法。

【0120】

(16) 実施態様(15)に記載の方法であって、
前記カッターが、前記切削面に対して垂直に延びたシャフトを含み、
前記シャフトを前記曲面の接線に対して垂直に維持しながら、前記カッターを前記骨に沿って横断させるステップをさらに含む、方法。

(17) 実施態様(16)に記載の方法であって、
前記曲面の接線に垂直な軸に沿ってシャフトを長手方向に移動させて、前記切削面を前記骨内に前進させるステップをさらに含む、方法。

(18) 実施態様(17)に記載の方法であって、
前記シャフトをその軸を中心に回転させるステップをさらに含む、方法。

(19) 実施態様(18)に記載の方法であって、
前記カッターを操作して前記トラックを連続的に移動させるステップをさらに含む、方法。

【図面の簡単な説明】

【0121】

【図1】ここに開示する骨整形器具の、ガイドの第1の実施形態、C A S位置確認装置、並びにカッター、保持カラー、および深さストッパーを含む誘導切削器具の第1の実施形態の組立分解図である。

【図2】図1の骨整形器具のガイドの平面図である。

【図3】図2のガイドの側面図である。

【図4】図3のガイドの端面図である。

【図5】ここに開示する骨整形器具の、図1のガイドの第1の実施形態、並びに後部カッター、前部カッター、およびドライバを含む誘導切削器具の第2の実施形態の側面図である。

【図6】図5の誘導切削器具およびガイドの平面図である。

【図7】図6の線7-7に沿って見たガイドおよび誘導切削器具の断面図である。

【図8】患者の大腿骨の遠位端部の内側顆にピンで留められた図1の骨整形器具の斜視図である。

【図9】大腿骨の内側顆の切除を開始する前の、ガイドに受容された誘導切削器具の第1の実施形態を示す、図8の骨整形器具の側面図である。

【図10】図9に示されている位置から大腿骨内に導入され、所望の切削深さまで大腿骨の内側顆の中に挿入された誘導切削器具を示す図9に類似した側面図である。

【図11】ガイドに案内されて前側に移動し、所望の切削深さまで大腿骨の内側顆の中に挿入された誘導切削器具を示す図10に類似した側面図である。

【図12】ガイドの内側レールおよび外側レールが、保持カラーから延出した2セットの4つのガイドピンを案内する、誘導切削器具の第3の実施形態およびガイドの第2の実施形態の側面図である。

【図13】ここに開示する骨整形器具の、ガイド溝を含むように構成されたガイドの第3の実施形態、並びにガイドのガイド溝に保持されるように構成されたガイドピンを受容するように構成された保持カラーおよびカッターを含む誘導切削器具の第4の実施形態の組立分解図である。

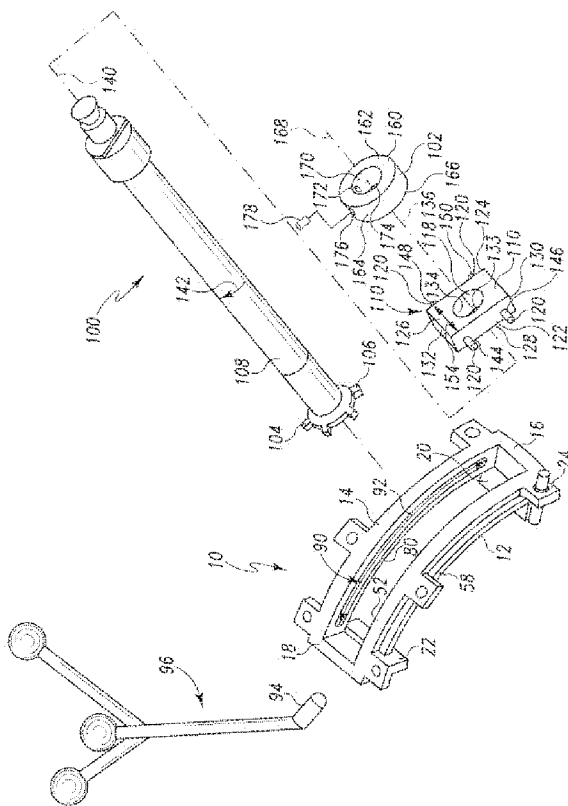
【図14】ガイドの第3の実施形態、並びに切除する骨に固定された図13の誘導切削器具の第4の実施形態の斜視図である。

【図15】ここに開示する骨整形器具の、誘導切削器具の第5の実施形態、並びに骨に形成されたスロット内をスライドして切除する骨に取り付けできるように構成されたガイドの第4の実施形態の斜視図である。

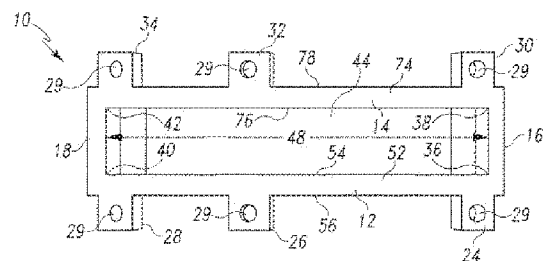
【図16】図15の骨整形器具の、誘導切削器具の第5の実施形態、およびガイドの第4の実施形態の斜視図である。

【図17】切除する骨に取り付けられた図15の骨整形器具の誘導切削器具の第5の実施形態およびガイドの第4の実施形態の斜視図である。

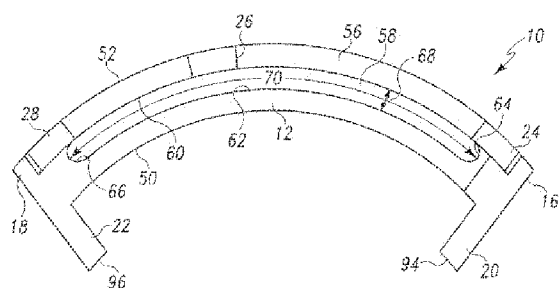
【図1】



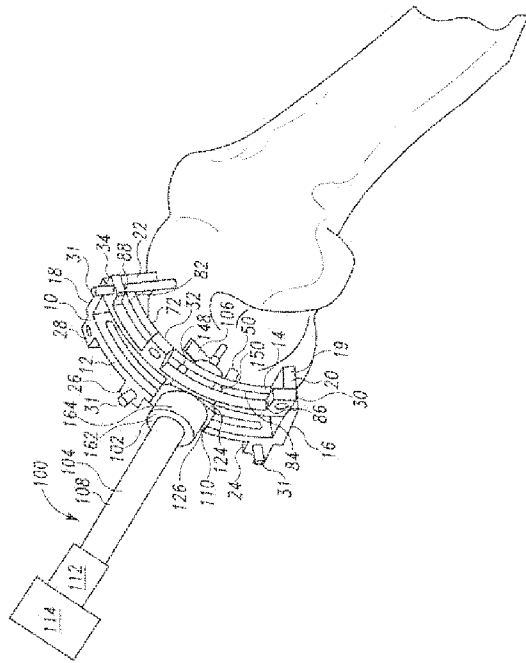
【図2】



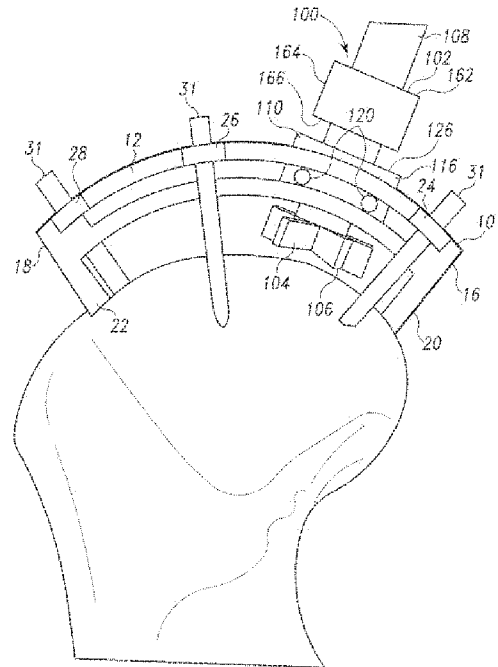
【図3】



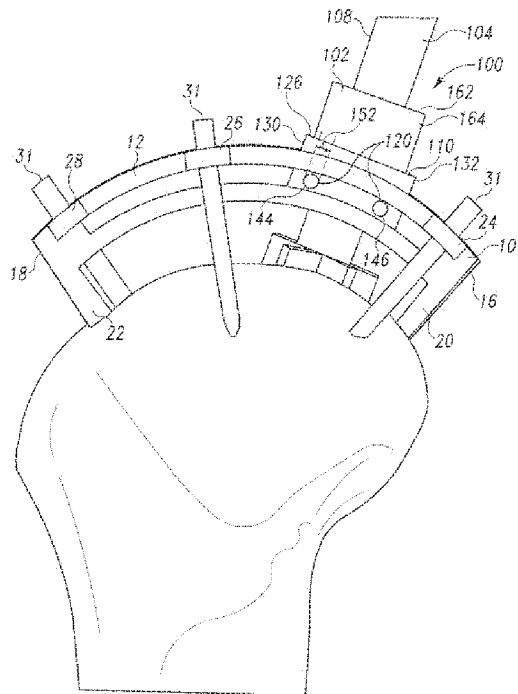
【図8】



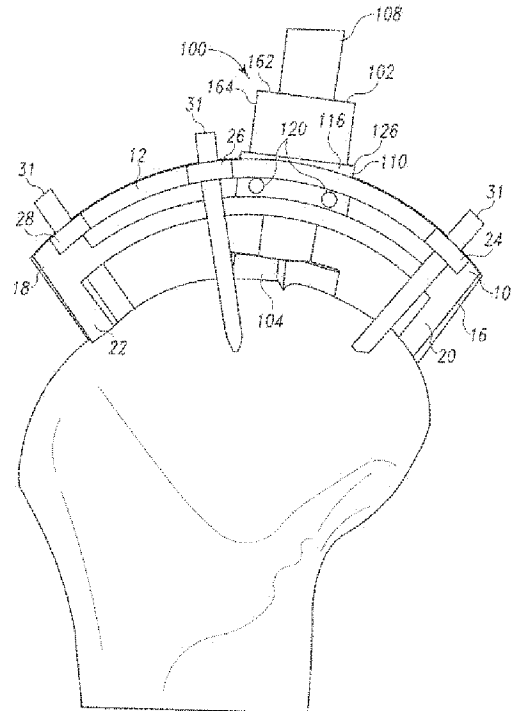
【図9】



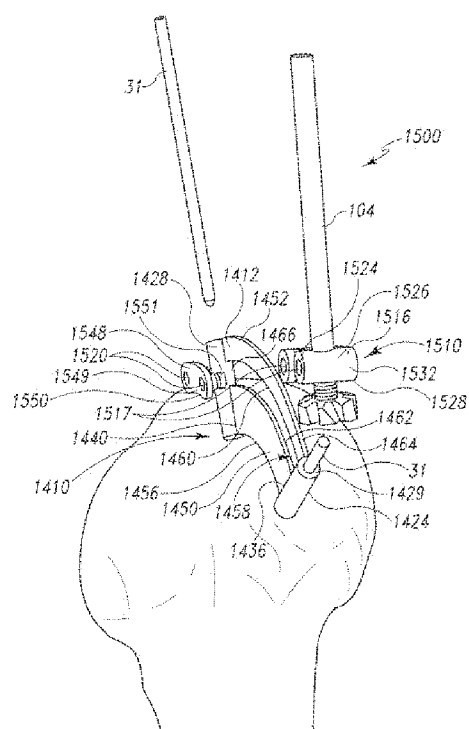
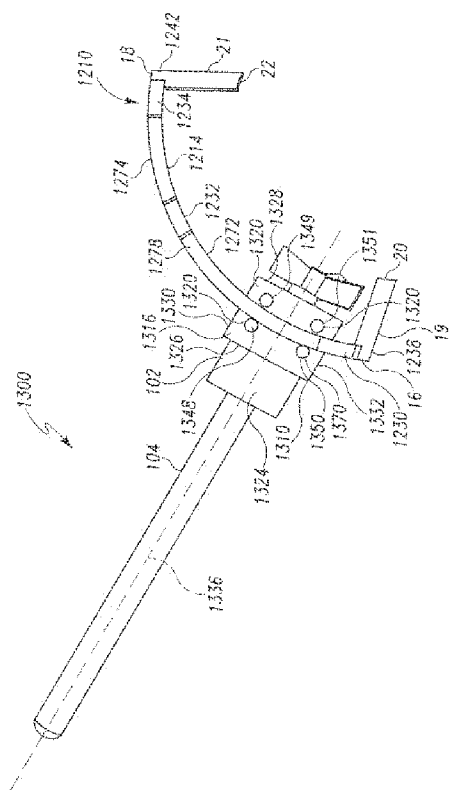
【図10】



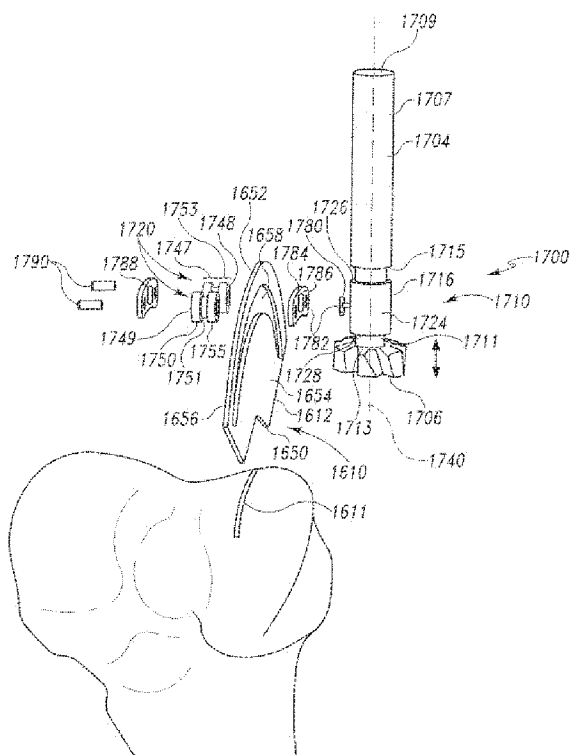
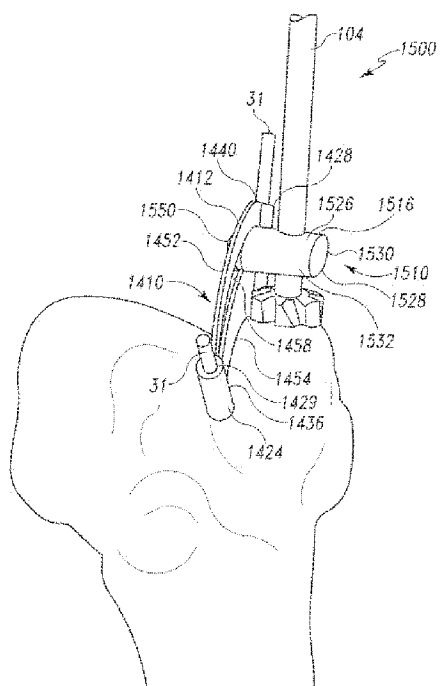
【図11】



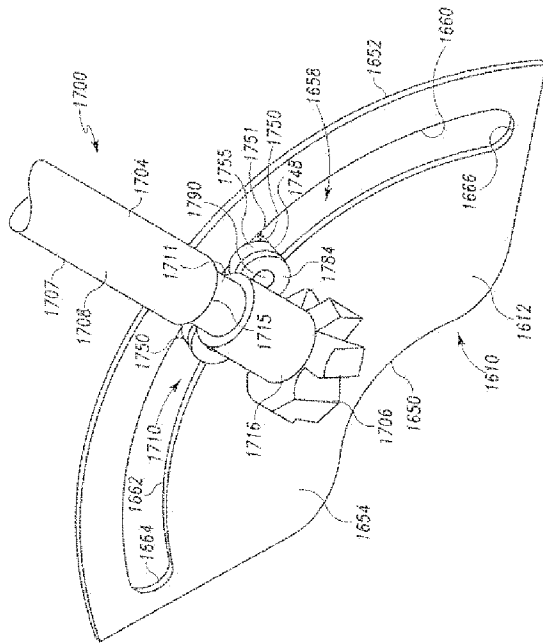
【圖13】



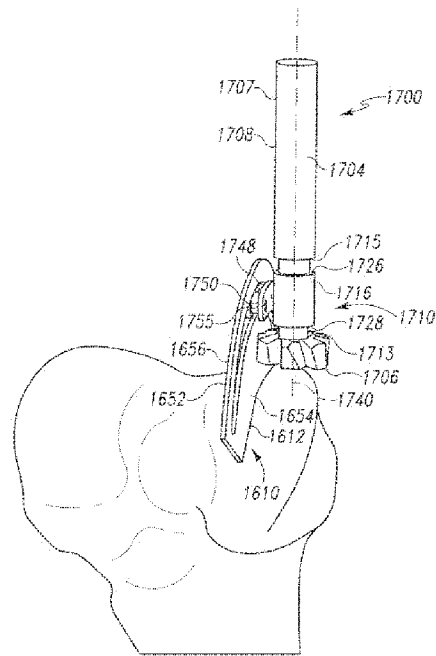
{ 15 }



【図16】



【図17】



(72)発明者 トラビス・ベネット

アメリカ合衆国、46814 インディアナ州、フォート・ウェイン、バックソーン 14823

(72)発明者 ジョセフ・ジー・ウィス

アメリカ合衆国、46750 インディアナ州、ハンチントン、ノース・ジェファソン・ストリート 1307

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

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		16448357
	Filing Date		2019-06-21
	First Named Inventor	F. Barry Bays	
	Art Unit		
	Examiner Name		
	Attorney Docket Number	71212.4.8.6	

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear		
	1	8080045	B2	2011-12-20	Wotton, III			
	2	10779867	B2	2020-09-22	Penzimer et al.			
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	1	20130085502	A1	2013-04-04	Harrold			
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NON-PATENT LITERATURE DOCUMENTS								Remove

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	
Examiner Name	
Attorney Docket Number	71212.4.8.6

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
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EXAMINER SIGNATURE

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

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	
Examiner Name	
Attorney Docket Number	71212.4.8.6

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2021-02-11
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

Privacy Act Statement

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

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

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

Electronic Acknowledgement Receipt

EFS ID:	41908203
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	12-FEB-2021
Filing Date:	21-JUN-2019
Time Stamp:	16:47:53
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	71212-4-8-6_SIDS.pdf	1034308	no	4
			21562b419e41ea4ca0f6681db55dba15061742cc		

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223

22859 7590 08/20/2021
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER

BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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08/20/2021

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Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

This application contains claims directed to the following patentably distinct species:

Bone Realignment Fulcrum Species A: Fig. 31

Bone Realignment Fulcrum Species B: Fig. 32

Bone Realignment Fulcrum Species C: Fig. 33

Bone Realignment Fulcrum Species D: Fig. 39A

Bone Realignment Fulcrum Species E: Fig. 39B

Bone Realignment Fulcrum Species F: Fig. 41

Bone Realignment Fulcrum Species G: Figs. 42A-42B

Bone Realignment Fulcrum Species H: Figs. 43A-43B

The species are independent or distinct because the claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single species from the Sternum Fixation Device species grouping, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

There is a search and/or examination burden for the patentably distinct species as set forth above because at least the following reason(s) apply:

the species or groupings of patentably indistinct species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search strategies or search queries).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or a grouping of patentably indistinct species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species or grouping of patentably indistinct species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species or grouping of patentably indistinct species.

Should applicant traverse on the ground that the species, or groupings of patentably indistinct species from which election is required, are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing them to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER J BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on Mon - Fri 8:30-5:00.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 571-272-4705. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER J BECCIA/
Primary Examiner, Art Unit 3775

22859
Customer Number

PATENT
Attorney Docket No.: 71212.4.8.6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: F. Barry Bays
Application No.: 16/448,357 Group Art Unit: 3775
Filed: June 21, 2019 Examiner: BECCIA.
 CHRISTOPHER J
Title: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING
 FULCRUM

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

RESPONSE TO RESTRICTION REQUIREMENT

Dear Commissioner:

This submission is in response to the Restriction Requirement mailed August 20, 2021, the period of response for which runs through October 20, 2021. The Restriction Requirement presented a requirement for an election of species. The following species were identified in the Restriction Requirement:

Bone Realignment Fulcrum Species A:	Figure 31;
Bone Realignment Fulcrum Species B:	Figure 32;
Bone Realignment Fulcrum Species C:	Figure 33;
Bone Realignment Fulcrum Species D:	Figure 39A;
Bone Realignment Fulcrum Species E:	Figure 39B;
Bone Realignment Fulcrum Species F:	Figure 41;
Bone Realignment Fulcrum Species G:	Figures 42A–42B;
Bone Realignment Fulcrum Species H:	Figure 43A–43B

Applicant hereby elects Species D and E, encompassing FIGS. 39A and 39B, with traverse. At least claims 1–8 and 12–15 read on, or are generic to, Species D and E.

For reasons set forth below, Applicant believes that Species D and E should be rejoined and the Applicant allowed to elect the subject matter of both species for further examination. In the event the Examiner disagrees and requires election of a single species, Applicant alternatively elects Species D, encompassing FIG. 39A, with traverse. At least claims 1–8 and 12–15 read on, or are generic to, Species D.

Traversal

Applicant respectfully traverses the restriction between Species D and E at least because there is a disclosed relationship between the two species. According to MPEP § 808.01(a), “Where there is a relationship disclosed between species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction.”

In the present case, there is a disclosed relationship between Species D and E. Applicant’s specification describes that “FIGS. 39A and 39B illustrate another example configuration of fulcrum 356 that can be used according to the disclosure.”¹ The application continues by stating that “FIG. 39A is a perspective view of one side of fulcrum 356, while FIG. 39B is a perspective view of the fulcrum from the opposite side.”² Thus, FIGS. 39A and 39B illustrate different sides of the same example fulcrum.

The Restriction Requirement did not appear to recognize this relationship between FIGS. 39A and 39B, designated as Species D and E. Nor did the Restriction Requirement discuss and advance reasons for imposing a restriction requirement between the two figures notwithstanding the disclosed relationship. Accordingly, for at least this reason, Applicant respectfully requests rejoinder of Species D and E.

Additionally, Applicant notes that MPEP § 803 sets out two criteria for requiring restriction between patentably distinct inventions:

- (A) the inventions must be independent³ or distinct⁴ as claimed; and
- (B) there would be a serious burden on the examiner if restriction is not required (emphasis added).

¹ Applicant’s specification at paragraph [0140].

² *Id.*

³ See MPEP §§ 802.01, 806.04, 808.01.

⁴ See MPEP §§ 806.05–806.05(i).

Against this standard, the Restriction Requirement offered reasons why there “is a search and/or examination burden for the patentably distinct species.”⁵ However, a search and/or examination burden does not substantiate a “serious burden” within the meaning of MPEP § 803. For this additional reason, Applicant respectfully submits that the requirements for imposing a species restriction have not been substantiated.

CONCLUSION

For at least the reasons given above, Applicant respectfully submits that the requirement for election between Species, particularly Species D and E, should be reconsidered and withdrawn.

The Examiner is invited to telephone the undersigned in the event there are any questions concerning the election or if the Examiner believes it would be useful to advance prosecution. Please charge any additional fees or credit any overpayment to deposit account number 06-1910.

Dated: October 19, 2021

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

74014018 v1

⁵ Restriction Requirement dated August 20, 2021, at page 2.

Electronic Acknowledgement Receipt

EFS ID:	44073268
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	20-OCT-2021
Filing Date:	21-JUN-2019
Time Stamp:	17:38:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	71212-4-8-6-RR.pdf	136280	no	3
			9560ba5f6de9d03222eea5609569e8ea149b144c		

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223

22859 7590 12/20/2021
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER

BECCIA, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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3775

NOTIFICATION DATE	DELIVERY MODE
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12/20/2021

ELECTRONIC

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

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

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

IP@FREDLAW.COM

Office Action Summary

Application No.

16/448,357

Applicant(s)

Bays et al.

Examiner

CHRISTOPHER J BECCIA

Art Unit

3775

AIA (FITF) Status

Yes

-- 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 MONTHS 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 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 October 20, 2021.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ 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*

- 5) ☒ Claim(s) 1-19 is/are pending in the application.
5a) Of the above claim(s) 9-11 and 16-19 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-8 and 14-15 is/are rejected.
- 8) ☒ Claim(s) 12-13 is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on June 21, 2019 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).

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).

Certified copies:

- a) ☐ All b) ☐ Some** c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** 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) ☒ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b)
Paper No(s)/Mail Date ____.
- 3) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 4) ☐ Other: ____.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

Applicant's election with traverse of Bone Realignment Fulcrum Species D and E, drawn to claims 1-8 and 12-15 in the reply filed on October 20, 2021 is acknowledged. The traversal is on the ground(s) that Species D and E encompass the same embodiment. Examiner acknowledges this assertion, and will further examine based on this election.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application,

or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-8 and 12-15 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 10,939,939. Although the claims at issue are not identical, they are not patentably distinct from each other because both the present application and granted patent disclose a fulcrum for use in a bone realignment procedure including a body configured to be inserted in an intermetatarsal space and a handle operatively connected to the body that projects at a non-zero degree angle from the body.

Allowable Subject Matter

Claims 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Most pertinent prior art, including U.S. Patent Pub. No. 2009/0216089 to *Davidson* and U.S. Patent No. 6,416,465 to *Brau*, disclose surface features configured to inhibit movement, but fail to teach or disclose wherein the first face has surface features configured to inhibit proximal to distal movement of the first face along a metatarsal against which the first face is positioned, and the second face has surface features configured to inhibit dorsal to plantar movement of the second face along a metatarsal against which the second face is positioned.

Claim Rejections - 35 USC § 102

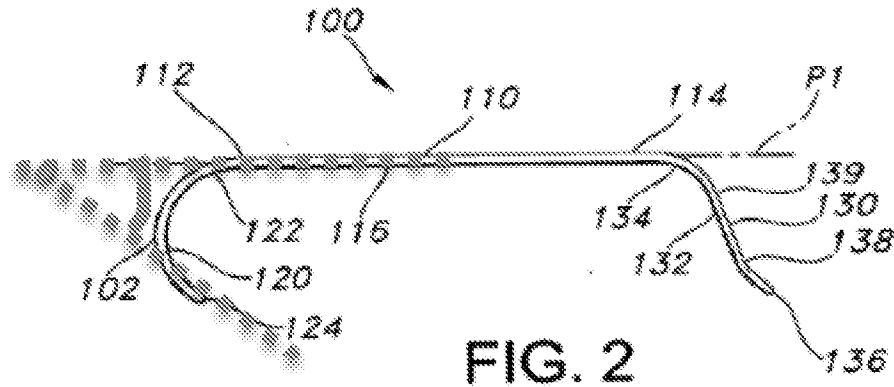
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claims 1, 3, 4, 7, and 8, are rejected under 35 U.S.C. 102(a)(1) as being anticipated by U.S. Patent Pub. No. 2009/0216089 to *Davidson*.

As to **Claim 1**, *Davidson* discloses a fulcrum (100) for use in a bone realignment procedure [0057-0058]. The fulcrum comprises a body (110) configured to be inserted in an intermetatarsal space (Fig. 19) between adjacent metatarsals [0058], and a handle (120) operatively connected to the body, wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body (angle seen in Fig. 2).



As to **Claim 3**, *Davidson* discloses a fulcrum wherein the body (110) defines an axis (P1) extending along the length of the body, the handle defines a handle axis (forming angle seen above) projecting at the non-zero degree angle from the body, and an angle between the axis of the body and the handle axis ranges from 20 degrees to 75 degrees (see Fig. 2 above).

As to **Claim 4**, *Davidson* discloses a fulcrum wherein the angle ranges from 35 degrees to 55 degrees (see Fig. 2 above).

As to **Claim 7**, *Davidson* discloses a fulcrum wherein the body and the handle are formed as a unitary structure ([0034], Fig. 1).

As to **Claim 8**, *Davidson* discloses a fulcrum wherein the body is configured to be inserted between a first metatarsal and a second metatarsal [0032, 0058].

Claim Rejections - 35 USC § 103

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

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C.

103 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 2, 5, 6, 14, and 15 are rejected under 35 U.S.C. 103 as being unpatentable over U.S.

Patent Pub. No. 2009/0216089 to *Davidson* in view of U.S. Patent No. 6,416,465 to *Brau*.

As to **Claim 2**, *Davidson* discloses a fulcrum wherein the handle includes a distal portion (124) and a handle body (near ref. 120, Fig. 1) positioned between the body of the fulcrum (110) and the distal portion (124, Figs. 1-2).

As to **Claim 5**, *Davidson* discloses a fulcrum wherein the body (110) defines an axis (P1) extending along the length of the body, the handle defines a handle axis (forming angle seen above) projecting at the non-zero degree angle from the body, and an angle between the axis of the body and the handle axis ranges from 20 degrees to 75 degrees (see Fig. 2 above).

As to **Claim 6**, *Davidson* discloses a fulcrum wherein the body (110) extends from a leading end (towards 136) to a trailing end (towards 122), the handle (120) projects off the trailing end, and the leading end is tapered (at 136, Fig. 1,

Ad to **Claims 2, 5, 6, 14, and 15**, *Davidson* discloses the claimed invention except for wherein the handle includes a grip portion, wherein the grip axis is perpendicular to the axis defined by the body of the fulcrum, wherein the body is rectangular shaped.

Brau discloses a surgical retractor (10, Fig. 1) wherein a handle (15) includes a grip portion (18), wherein a grip axis (along body of 15, Fig. 1, Col. 5, Lines 52-58) is perpendicular to the axis defined by the body (20) of the fulcrum (Fig. 1). The body (20) of the fulcrum is rectangular shaped (Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the tool of *Davidson* with the grip modification of *Brau* in order to provide stability as the device is held by the practitioner (Col. 5, Lines 52-58).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER J BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached Mon - Fri 8:30-5:00.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 571-272-4705. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

Art Unit: 3775

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

/CHRISTOPHER J BECCIA/

Primary Examiner, Art Unit 3775

Notice of References Cited	Application/Control No. 16/448,357		Applicant(s)/Patent Under Reexamination Bays et al.	
	Examiner CHRISTOPHER J BECCIA		Art Unit 3775	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-6416465-B2	07-2002	Brau; Salvador A.	A61B17/02	600/210
*	B	US-20090216089-A1	08-2009	Davidson; Richard S.	A61B17/02	600/235
*	C	US-10939939-B1	03-2021	Gil; Carlos Eduardo	A61B17/56	1/1
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	M					

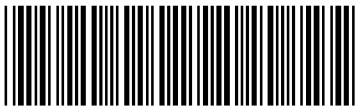
FOREIGN PATENT DOCUMENTS

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

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	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.

<i>Search Notes</i> 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

CPC - Searched*		
Symbol	Date	Examiner
A61B17/88, 8866, 80, 8061, 15, 1521	12/15/2021	CJB

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
Search History Attached	12/15/2021	CJB
Inventor Search	12/15/2021	CJB
Text Search	12/15/2021	CJB
Classification Search	12/15/2021	CJB
B/F Citations	12/15/2021	CJB

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	
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Doc code: IDS

PTO/SB/08a (02-18)

Doc description: Information Disclosure Statement (IDS) Filed

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

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

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5374271	A	1994-12-20	Hwang	
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	1	20110009865	A1	2011-01-13	Orfaly	
	2	20120130382	A1	2012-05-24	Iannotti et al.	
	3	20110118739	A1	2011-05-19	TYBER et al.	
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
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EXAMINER SIGNATURE

Examiner Signature	/CHRISTOPHER J BECCIA/	Date Considered	08/15/2021
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First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

CERTIFICATION STATEMENT

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

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

OR

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

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2020-04-13
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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Doc code: IDS

PTO/SB/08a (02-18)

Doc description: Information Disclosure Statement (IDS) Filed

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

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First Named Inventor	F. Barry Bays
Art Unit	
Examiner Name	
Attorney Docket Number	71212.4.8.6

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	1	8080045	B2	2011-12-20	Wotton, III	
	2	10779867	B2	2020-09-22	Penzimer et al.	

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	1	20130085502	A1	2013-04-04	Harrold	

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First Named Inventor	F. Barry Bays	
Art Unit		
Examiner Name		
Attorney Docket Number	71212.4.8.6	

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Art Unit			
Examiner Name			
Attorney Docket Number	71212.4.8.6		

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OR

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2021-02-11
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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PE2E SEARCH - Search History (Prior Art)

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		"7972338" "8057478" "8080010" "8123753" "8137406" "8147530" "8167918" "8172848" "8192441" "8197487" "8231663" "8246561" "8262664" "8282644" "8282645" "8292966" "8313492" "8323289" "8337503" "8343159" "8377105" "8435246" "8475462" "8523870" "8652142" "8672945" "8696716" "8715363" "8728084" "8758354" "8764763" "8771279" "8784427" "8784457" "8795286" "8801727" "8808303" "8828012" "8858602" "8882778" "8998903" "8998904" "9023052" "9044250" "9060822" "9089376" "9101421" "9107715" "D610257" "D629900" "D646389" "D651315" "D651316" "D666721" "D679395" "D694884" "D695402" "D701303" "D705929" "D765844" "D766434" "D766437" "D766438" "H001706").PN. OR ("9622805").URPN.					
L52	0	(13/632666).APP.	(USPAT; USOCR)	OR	OFF	OFF	2018/12/18 09:40 AM
L53	290	cuneiform with metatarsal	(USPAT; USOCR)	OR	OFF	OFF	2018/12/18 09:43 AM
L54	626	cuneiform with metatarsal	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/12/18 09:44 AM
L55	95	L54 and bunion	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/12/18 09:51 AM
L56	100	L54 and hallux valgus	(US-PGPUB; USPAT; USOCR)	ADJ	OFF	OFF	2018/12/18 09:53 AM
L64	19	santrock-robert-d.in.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:36 PM
L67	3477	a61b17/88.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:40 PM
L68	1337	a61b17/8888.cpc.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/12/18

L69	2217	a61b17/8866.cpc.	USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	06:41 PM
L70	7193	a61b17/80.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:41 PM
L71	6171	a61b17/8061.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:41 PM
L72	7545	a61b17/02.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:41 PM
L73	6899	a61b17/025.cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/12/18 06:41 PM
L74	3	("20020107519" "20040 010259" "20130325019 ").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/05/07 07:25 PM
L75	1	(13/485444).APP.	(USPAT; USOCR)	OR	OFF	OFF	2019/05/07 07:25 PM
L76	8	("20020099381" "20080 172054" "20120277745 " "20120330135" "2013 0096563" "2015004580 1" "20180344334" "541 7694").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/05/07 07:29 PM
L77	5	("20080009863" "20140 257308" "4995875" "56 01565" "6511481").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/05/07 07:30 PM
L78	1	"16448357"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/08/15 10:57 AM
L79	2	"10342590".pn.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB,	OR	ON	ON	2021/08/15 10:59 AM

L80	251	("4159716" "4187840" "4338927" "4570624" "4627425" "4628919" "4757810" "4895141" "4952214" "4978347" "4988349" "4995875" "5021056" "5112334" "5207676" "5254119" "5312412" "5358504" "5364402" "5413579" "5417694" "5449360" "5529075" "5601565" "5620442" "H1706" "5788695" "5803924" "5810822" "5893553" "5935128" "5941877" "5951556" "6030391" "6162223" "6171309" "6511481" "6719773" "6743233" "7033361" "7182766" "7241298" "7377924" "7465303" "7641660" "D610257" "7686811" "D629900" "7972338" "D646389" "8057478" "D651315" "D651316" "8080010" "8123753" "8137406" "8147530" "8167918" "8172848" "8192441" "8197487" "8231623" "8231663" "8246561" "D666721" "8262664" "8282644" "8282645" "8292966" "8313492" "8323289" "8337503" "8343159" "8377105" "D679395" "8435246" "8475462" "8523870" "D694884" "D695402" "8652142" "D701303" "8672945" "8696716" "D705929" "8715363" "8728084" "8758354" "8764763" "8771279" "8784427" "8784457" "8795286" "8801727" "8808303" "8828012" "8858602" "8882778" "8998903" "8998904" "9023052" "9044250" "9060822" "9089376" "9101421" "9107715"	HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/15 10:59 AM
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		"D765844" "D766434" "D766437" "D766438" "9750538" "20020099381" "20020107519" "20020198531" "20040010259" "20040039394" "20040097946" "20050004676" "20050075641" "20050101961" "20050149042" "20050228389" "20050273112" "20060206044" "20060217733" "20060229621" "20060241607" "20060241608" "20060264961" "20070123857" "20070233138" "20070265634" "20070276383" "20080009863" "20080091197" "20080140081" "20080172054" "20080208252" "20080262500" "20080269908" "20090036893" "20090093849" "20090105767" "20090118733" "20090198244" "20090198279" "20090222047" "20090254092" "20090254126" "20090287309" "20100069910" "20100121334" "20100130981" "20100152782" "20100168799" "20100185245" "20100249779" "20100256687" "20100324556" "20110093084" "20110245835" "20110288550" "20110301648" "20120016426" "20120065689" "20120078258"					
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		"20120123420"					
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L82	48	santrock-robert-d.in.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/08/15 11:00 AM
L83	86	treace-john-t.in.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO);	OR	ON	ON	2021/08/15 11:00 AM

L84	156	dayton-paul.in.	FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/08/15 11:00 AM
L85	249	("20020099381" OR "20020107519" OR "20020198531" OR "20040010259" OR "20040039394" OR "20040097946" OR "20050004676" OR "20050059978" OR "20050075641" OR "20050101961" OR "20050149042" OR "20050228389" OR "20050273112" OR "20060206044" OR "20060217733" OR "20060229621" OR "20060241607" OR "20060241608" OR "20060264961" OR "20070123857" OR "20070233138" OR "20070265634" OR "20070276383" OR "20080009863" OR "20080091197" OR "20080140081" OR "20080172054" OR "20080208252" OR "20080262500" OR "20080269908" OR "20090036893" OR "20090093849" OR "20090105767" OR "20090118733" OR "20090198244" OR "20090198279" OR "20090222047" OR "20090254092" OR "20090254126" OR "20090287309" OR "20100069910" OR "20100121334" OR "20100130981" OR "20100152782" OR	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:01 AM

		"20100168799" OR "20100185245" OR "20100249779" OR "20100256687" OR "20100324556" OR "20110093084" OR "20110245835" OR "20110288550" OR "20110301648" OR "20120016426" OR "20120065689" OR "20120078258" OR "20120123420" OR "20120123484" OR "20120130376" OR "20120130383" OR "20120184961" OR "20120239045" OR "20120253350" OR "20120265301" OR "20120277745" OR "20120330135" OR "20130012949" OR "20130035694" OR "20130085499" OR "20130096563" OR "20130150903" OR "20130158556" OR "20130165936" OR "20130165938" OR "20130172942" OR "20130184714" OR "20130190765" OR "20130190766" OR "20130204259" OR "20130231668" OR "20130237987" OR "20130237989" OR "20130267956" OR "20130310836" OR "20130325019" OR "20130325076" OR "20130331845" OR "20130338785" OR "20140005672" OR "20140025127" OR "20140039501" OR "20140039561" OR "20140046387" OR "20140074099" OR "20140074101" OR "20140094861" OR "20140094924" OR "20140163563" OR "20140171953" OR "20140180342" OR "20140194884" OR "20140207144" OR					
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		"20140249537" OR "20140257308" OR "20140257509" OR "20140276815" OR "20140276853" OR "20140277176" OR "20140277214" OR "20140296995" OR "20140303621" OR "20140336658" OR "20150032168" OR "20150045801" OR "20150045839" OR "20150051650" OR "20150066094" OR "20150112446" OR "20150119944" OR "20150142064" OR "20150150608" OR "20150182273" OR "20150223851" OR "20150245858" OR "20160015426" OR "20160022315" OR "20160151165" OR "20160175089" OR "20160192950" OR "20160199076" OR "20160213384" OR "20160235414" OR "20160242791" OR "20160256204" OR "20160354127" OR "20170079669" OR "20180344334" OR "4159716" OR "4187840" OR "4338927" OR "4570624" OR "4627425" OR "4628919" OR "4757810" OR "4895141" OR "4952214" OR "4978347" OR "4988349" OR "4995875" OR "5021056" OR "5112334" OR "5207676" OR "5254119" OR "5312412" OR "5358504" OR "5364402" OR "5413579" OR "5417694" OR "5449360" OR "5529075" OR					
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	"5601565" OR "5620442" OR "5788695" OR "5803924" OR "5810822" OR "5893553" OR "5935128" OR "5941877" OR "5951556" OR "6030391" OR "6162223" OR "6171309" OR "6511481" OR "6719773" OR "6743233" OR "7033361" OR "7182766" OR "7241298" OR "7377924" OR "7465303" OR "7641660" OR "7686811" OR "7972338" OR "8057478" OR "8080010" OR "8123753" OR "8137406" OR "8147530" OR "8167918" OR "8172848" OR "8192441" OR "8197487" OR "8231623" OR "8231663" OR "8246561" OR "8262664" OR "8282644" OR "8282645" OR "8292966" OR "8313492" OR "8323289" OR "8337503" OR "8343159" OR "8377105" OR "8435246" OR "8475462" OR "8523870" OR "8652142" OR "8672945" OR "8696716" OR "8715363" OR "8728084" OR "8758354" OR "8764763" OR "8771279" OR "8784427" OR "8784457" OR "8795286" OR					
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		"8801727" OR "8808303" OR "8828012" OR "8858602" OR "8882778" OR "8998903" OR "8998904" OR "9023052" OR "9044250" OR "9060822" OR "9089376" OR "9101421" OR "9107715" OR "9750538" OR "D610257" OR "D629900" OR "D646389" OR "D651315" OR "D651316" OR "D666721" OR "D679395" OR "D694884" OR "D695402" OR "D701303" OR "D705929" OR "D765844" OR "D766434" OR "D766437" OR "D766438" OR "D766439" OR "H001706").pn. ("10292713" OR "20020165552" OR "20040138669" OR "20050070909" OR "20050251147" OR "20060129163" OR "20070010818" OR "20080039850" OR "20080147073" OR "20080195215" OR "20090036931" OR "20090054899" OR "20120185056" OR "20120191199" OR "20130226248" OR "20130226252" OR "20140188139" OR "20140194999" OR "20140343555" OR "20150057667" OR "20160324532" OR "20170042598" OR "4069824" OR "4335715" OR "4349018" OR "4409973" OR "4440168" OR					
L86	88	(US-PGPUB; USPAT) OR ON ON 2021/08/15 11:03 AM					

		"4501268" OR "4502474" OR "4509511" OR "4565191" OR "4632102" OR "4664102" OR "4708133" OR "4750481" OR "5035698" OR "5042983" OR "5049149" OR "5053039" OR "5078719" OR "5147364" OR "5176685" OR "5246444" OR "5470335" OR "5540695" OR "5578038" OR "5613969" OR "5620448" OR "5643270" OR "5667510" OR "5722978" OR "5749875" OR "5779709" OR "5843085" OR "5911724" OR "5980526" OR "5984931" OR "6007535" OR "6027504" OR "6203545" OR "6248109" OR "6391031" OR "6547793" OR "6676662" OR "6755838" OR "6796986" OR "7018383" OR "7112204" OR "7540874" OR "7572258" OR "7691108" OR "7763026" OR "7967823" OR "8062301" OR "8083746" OR "8236000" OR "8277459" OR "8409209" OR "8496662" OR "8529571" OR "8540777" OR "8657820" OR "8702715" OR "8777948" OR "8888785" OR					
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L87	21	"8900247" OR "8906026" OR "9113920").pn. ("10028750" OR "10064631" OR "10159499" OR "10327829" OR "20100318088" OR "20130131821" OR "20140135775" OR "20140288562" OR "20170143511" OR "20170164989" OR "5490854" OR "6478799" OR "6859661" OR "7282054" OR "8303596" OR "8764760" OR "8882816" OR "8945132" OR "9785747" OR "D720456" OR "D740424").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:04 AM
L88	4	("20110009865" OR "20110118739" OR "20120130382" OR "5374271").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:05 AM
L89	3	("20080288004" OR "3664022" OR "9522023").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:08 AM
L90	3	("20080288004" OR "3664022" OR "9522023").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:09 AM
L91	6	("10470779" OR "20080015603" OR "20110178524" OR "4736737" OR "4959066" OR "8545508").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:10 AM
L92	3	("10779867" OR "20130085502" OR "8080045").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:11 AM
L93	3	("10779867" OR "20130085502" OR "8080045").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2021/08/15 11:12 AM
L94	97	treace-john-t.in.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO);	OR	ON	ON	2021/12/04 11:14 AM

L95	97	treace-john-t.in.	FPRS; EPO; JPO; DERWENT; IBM_TDB) (US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/04 11:14 AM
L96	18	treace-john-t.in.	(USPAT)	OR	ON	ON	2021/12/04 11:14 AM
L97	1	"16448357"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DK, EA, EE, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/12/13 10:57 AM
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PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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N32	5	(bunion deformity).clm.	(USPAT)	AND	ON	ON	2017/02/10 06:43 PM
N33	1	(bunion deformity plane).clm.	(USPAT)	AND	ON	ON	2017/02/10 06:44 PM
N34	0	(bunion plane aligned).clm.	(USPAT)	AND	ON	ON	2017/02/10 06:44 PM
N79	1	(method bunion fulcrum).clm.	(USPAT)	AND	ON	ON	2019/05/07 07:41 PM
N80	1	(bunion fulcrum).clm.	(USPAT)	AND	ON	ON	2019/05/07 07:41 PM
N81	14	(metatarsal fulcrum).clm.	(USPAT)	AND	ON	ON	2019/05/07 07:41 PM
N82	5	(method bunion deformity fulcrum).clm.	(US-PGPUB; USPAT)	AND	ON	ON	2021/12/04 11:22 AM
N83	11	(method bunion deformity fixing).clm.	(US-PGPUB; USPAT)	AND	ON	ON	2021/12/04 11:23 AM

Doc code: IDS

PTO/SB/08a (03-15)

Doc description: Information Disclosure Statement (IDS) Filed

Approved for use through 07/31/2016. OMB 0651-0031

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number

Filing Date

First Named Inventor

F. Barry Bays

Art Unit

Examiner Name

Attorney Docket Number

71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1	2098036	RU	C1	1997-12-10	Skvortsov, et al.		
	2	2195892	RU	C2	2003-01-10	Kotel, et al.		
	3	2320287	RU	C1	2008-03-27	Ezhov		

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number		
Filing Date		
First Named Inventor	F. Barry Bays	
Art Unit		
Examiner Name		
Attorney Docket Number	71212.4.8.6	

4	2321369	RU	C1	2008-04-10	Valiakhmetov, et al.		
5	2321366	RU	C2	2008-04-10	Kotel, et al.		
6	2346663	RU	C2	2009-02-20	Barinov, et al.		
7	2412662	RU	C1	2011-02-27	Zyrjanov, et al.		
8	1333328	SU	A2	1987-08-30	Nadgertsev, et al.		
9	2008051064	WO	A1	2008-05-02	Jose		
10	0166022	WO	A1	2001-09-13	Pinczewski et al.		
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12	2011037885	WO	A1	2011-03-31	Sand, et al.		
13	2012029008	WO	A1	2012-03-08	Herzog et al.		
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
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Application Number		
Filing Date		
First Named Inventor	F. Barry Bays	
Art Unit		
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Attorney Docket Number	71212.4.8.6	

15	200903719	IN	P1	2009-06-08	Hasselman		
16	2013090392	WO	A1	2013-06-20	Sammarco		
17	2013134387	WO	A1	2013-09-12	Elghazaly		
18	2013169475	WO	A1	2013-11-14	Neal, et al.		
19	2014022055	WO	A1	2014-02-06	O'Connell, et al.		
20	2014020561	WO	A1	2014-02-06	Honiball		
21	2014035991	WO	A1	2014-03-06	Lang		
22	2014085882	WO	A1	2014-06-12	Angeli		
23	2014152535	WO	A1	2014-09-25	Mcginley, et al.		
24	2014152219	WO	A2	2014-09-25	Dacosta, et al.		
25	2014147099	WO	A1	2014-09-25	Claes, et al.		

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First Named Inventor	F. Barry Bays	
Art Unit		
Examiner Name		
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26	2014177783	WO	A1	2014-11-06	Leemrijse, et al.		
27	2014200017	WO	A1	2014-12-18	Tanji		
28	2015105880	WO	A1	2015-07-16	Montoya, et al.		
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30	140/DELNP/2012	IN	P1	2013-02-01	Johnson, et al.		
31	2009029798	WO	A1	2009-03-05	ACUMED LLC		

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NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	ALBANO et al., "Biomechanical Study of Transcortical or Transtrabecular Bone Fixation of Patellar Tendon Graft with Bioabsorbable Pins in ACL Reconstruction in Sheep," Revista Brasileira de Ortopedia (Rev Bras Ortop.) Vol. 47, No. 1, 2012, pp. 43-49.	
	2	ANDERSON et al., "Uncemented STAR Total Ankle Prostheses," The Journal of Bone and Joint Surgery, Vol. 86(1, Suppl 2), September 2004, pp. 103-111, (Abstract Only).	
	3	DAYTON et al., "Is Our Current Paradigm for Evaluation and Management of the Bunion Deformity Flawed? A Discussion of Procedure Philosophy Relative to Anatomy," The Journal of Foot and Ankle Surgery, Vol. 54, 2015, pp. 102-111.	

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Application Number	
Filing Date	
First Named Inventor	F. Barry Bays
Art Unit	
Examiner Name	
Attorney Docket Number	71212.4.8.6

4	DAYTON et al., "Observed Changes in Radiographic Measurements of the First Ray after Frontal and Transverse Plane Rotation of the Hallux: Does the Hallux Drive the Metatarsal in a Bunion Deformity?," The Journal of Foot and Ankle Surgery, Vol. 53, 2014, pp. 584-587.
5	DAYTON et al., "Relationship Of Frontal Plane Rotation Of First Metatarsal To Proximal Articular Set Angle And Hallux Alignment In Patients Undergoing Tarsometatarsal Arthrodesis For Hallux Abducto Valgus: A Case Series And Critical Review Of The Literature," The Journal of Foot and Ankle Surgery, Vol. 52, No. 3, May/June 2013, pp. 348-354.
6	DAYTON et al., "Quantitative Analysis of the Degree of Frontal Rotation Required to Anatomically Align the First Metatarsal Phalangeal Joint During Modified Tarsal-Metatarsal Arthrodesis Without Capsular Balancing," The Journal of Foot and Ankle Surgery, 2015, pp. 1-6.
7	DE GEER et al., "A New Measure of Tibial Sesamoid Position in Hallux Valgus in Relation to the Coronal Rotation of the First Metatarsal in CT Scans," Foot and Ankle International, March 26, 2015, 9 pages.
8	DiDOMENICO et al., "Correction of Frontal Plane Rotation of Sesamoid Apparatus during the Lapidus Procedure: A Novel Approach," The Journal of Foot and Ankle Surgery, Vol. 53, 2014, pp. 248-251.
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Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
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F. Barry Bays

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107	20150112446	A1	2015-04-23	Melamed et al.	
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114	20170079669	A1	2017-03-23	Bays et al.	

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Application Number		
Filing Date		
First Named Inventor	F. Barry Bays	
Art Unit		
Examiner Name		
Attorney Docket Number	71212.4.8.6	

115	20160022315	A1	2016-01-28	SOFFIATTI et al.
116	20160151165	A1	2016-06-02	Fallin et al.
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118	20160192950	A1	2016-07-07	Dayton et al.
119	20160199076	A1	2016-07-14	Fallin et al.
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122	20160242791	A1	2016-08-25	Fallin et al.
123	20160256204	A1	2016-09-08	PATEL et al.
124	20160354127	A1	2016-12-08	Lundquist et al.
125	20160015426	A1	2016-01-21	Dayton et al.

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127	20040010259	A1	2004-01-15	KELLER et al.
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129	20120277745	A1	2012-11-01	LIZEE et al.
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132	20140257308	A1	2014-09-11	JOHANNABER
133	20020099381	A1	2002-07-25	MARONEY
134	20080172054	A1	2008-07-17	CLAYPOOL et al.
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	137	20180344334	A1	2018-12-06	KIM et al.
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	1	2009227957	AU	B2	2014-07-10	Boutin, et al.		
	2	2491824	CA	A1	2005-09-08	Grimm, et al.		
	3	2854997	CA	A1	2013-05-16	Leslie, et al.		
	4	695846	CH	A5	2006-09-29	Roland, et al.		
	5	2930668	CN	Y	2007-08-08	Lin		
	6	201558162	CN	U	2010-08-25	Xiaojian, et al.		
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	8	201586060	CN	U	2010-09-22	Xiaojian, et al.		

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9	201912210	CN	U	2011-08-03	Xing, et al.		
10	202801773	CN	U	2013-03-20	Tang, et al.		
11	103462675	CN	A	2013-12-25	Tang, et al.		
12	103505276	CN	A	2014-01-15	Wang, et al.		
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14	203576647	CN	U	2014-05-07	Huang, et al.		
15	102860860	CN	B	2014-05-21	Xia, et al.		
16	104490460	CN	A	2015-04-08	Xu		
17	104510523	CN	A	2015-04-15	Xu		
18	104523327	CN	A	2015-04-22	Ma, et al.		
19	104546102	CN	A	2015-04-29	Ma, et al.		

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20	204379413	CN	U	2015-06-10	Xu		
21	204410951	CN	U	2015-06-24	Xu		
22	204428145	CN	U	2015-07-01	Xu		
23	204428144	CN	U	2015-07-01	Xu		
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25	204446081	CN	U	2015-07-08	Ma, et al.		
26	200904479	IN	P2	2010-05-21	Auger, et al.		
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29	2124772	EP	A1	2009-12-02	Richards		
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31	2632349	EP	A1	2013-09-04	Iannotti, et al.		
32	2665428	EP	A1	2013-11-27	Johannaber		
33	2742878	EP	A1	2014-06-18	Reynolds, et al.		
34	2750617	EP	A1	2014-07-09	Gaudin		
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36	2362616	FR	A1	1978-03-24	Duyck		
37	2764183	FR	B1	1999-11-05	Afriat, et al.		
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42	4162380	JP	B2	2008-10-08	Michael, et al.		
43	2011092405	JP	A	2011-05-12	Sato		
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45	4796943	JP	B2	2011-10-19	Yoshimura, et al.		
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50	100904142	KR	B1	2009-06-15	Warburton, et al.		

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Art Unit		
Examiner Name		
Attorney Docket Number	71212.4.8.6	

CERTIFICATION STATEMENT

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2019-06-19
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	TRUONG, KEVIN THAO
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear		
	1	3664022	A	1972-05-23	SMALL			
	2	9522023	B2	2016-12-20	HADDAD et al.			
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	1	20080288004	A1	2008-11-20	SCHENDEL			
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	ALVINE et al., "Peg and Dowel Fusion of the Proximal Interphalangeal Joint," Foot & Ankle, Vol. 1, No. 2, 1980, pp. 90-94.	
	2	BEDNARZ et al., "Modified Lapidus Procedure for the Treatment of Hypermobility Hallux Valgus," Foot & Ankle International, Vol. 21, No. 10, October 2000, pp. 816-821.	
	3	CARR et al., "Correctional Osteotomy for Metatarsus Primus Varus and Hallux Valgus," The Journal of Bone and Joint Surgery, Vol. 50-A, No. 7, October 1968, pp. 1353-1367.	
	4	COETZEE et al., "The Lapidus Procedure: A Prospective Cohort Outcome Study," Foot & Ankle International, Vol. 25, No. 8, August 2004, pp. 526-531.	
	5	DOTY et al., "Hallux valgus and hypermobility of the first ray: facts and fiction," International Orthopaedics, Vol. 37, 2013, pp. 1655-1660.	
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	7	LAPIDUS, "The Author's Bunion Operation From 1931 to 1959," Clinical Orthopaedics, Vol. 16, 1960, pp. 119-135.	
	8	OSHER et al., "Accurate Determination of Relative Metatarsal Protrusion with a Small Intermetatarsal Angle: A Novel Simplified Method," The Journal of Foot & Ankle Surgery, Vol. 53, No. 5, September/October 2014, published online: June 3, 2014, pp. 548-556.	
	9	PATEL et al., "Modified Lapidus Arthrodesis: Rate of Nonunion in 227 Cases," The Journal of Foot & Ankle Surgery, Vol. 43, No. 1, January/February 2004, pp. 37-42.	
	10	TOTH et al., "The Effect of First Ray Shortening in the Development of Metatarsalgia in the Second Through Fourth Rays After Metatarsal Osteotomy," Foot & Ankle International, Vol. 28, No. 1, January 2007, pp. 61-63.	

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11	DAYTON et al., "Comparison of the Mechanical Characteristics of a Universal Small Biplane Plating Technique Without Compression Screw and Single Anatomic Plate With Compression Screw," The Journal of Foot & Ankle Surgery, Vol. 55, No. 3, May/June 2016, published online: February 9, 2016, pp. 567-571.
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Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2020-06-15
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

Application Number	16448357
Filing Date	2019-06-21
First Named Inventor	F. Barry Bays
Art Unit	3775
Examiner Name	Not Yet Assigned
Attorney Docket Number	71212.4.8.6

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Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4069824	A	1978-01-24	WEINSTOCK	
	2	4335715	A	1982-06-22	Kirkley	
	3	4349018	A	1982-09-14	Chambers	
	4	4409973	A	1983-10-18	Neufeld	
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	1	20020165552	A1	2002-11-07	Duffner	
	2	20040138669	A1	2004-07-15	Horn	
	3	20170042598	A1	2017-02-16	Santroock et al.	
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	1	03075775	WO	A1	2003-09-18	KUPA PRAEZ SMASCHINEN GES M B		
	2	2004089227	WO	A2	2004-10-21	KUHN		
	3	2016134160	WO	A1	2016-08-25	TREACE MEDICAL CONCEPTS INC		

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	1	GREGG et al., "Plantar plate repair and Weil osteotomy for metatarsophalangeal joint instability," Foot and Ankle Surgery, Vol. 13, 2007, pp. 116-121.	
	2	WEIL et al., "Anatomic Plantar Plate Repair Using the Weil Metatarsal Osteotomy Approach," Foot & Ankle Specialist, Vol. 4, No. 3, 2011, pp. 145-150.	

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CERTIFICATION STATEMENT

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

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The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

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

Signature	/Paul J. LaVanway, Jr./	Date (YYYY-MM-DD)	2019-07-31
Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
16/448,357	06/21/2019	606	3775	71212.4.8.6
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APPLICANTS
 Treace Medical Concepts, Inc., Ponte Vedra, FL;

INVENTORS
 F. Barry Bays, Collierville, TN;
 Robert D. Santrock, Morgantown, WV;
 Paul Dayton, Fort Dodge, IA;
 Daniel J. Hatch, Greeley, CO;
 W. Bret Smith, Lexington, SC;
 Carlos Eduardo Gil, Jacksonville Beach, FL;
 Sean F. Scanlan, Jacksonville, FL;
 Joe William Ferguson, Ponte Vedra Beach, FL;
 John T. Treace, Ponte Vedra Beach, FL;

**** CONTINUING DATA *******
 This application is a DIV of 15/236,464 08/14/2016 PAT 10342590
 which claims benefit of 62/293,189 02/09/2016
 and is a CIP of 14/981,335 12/28/2015 PAT 9622805
 which claims benefit of 62/205,338 08/14/2015

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	1	4736737	A	1988-04-12	FARGIE et al.	
	2	4959066	A	1990-09-25	DUNN et al.	
	3	8545508	B2	2013-10-01	COLLAZO	
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Name/Print	Paul J. LaVanway, Jr.	Registration Number	64610

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/448,357		Filing Date 06/21/2019		☐ To be Mailed			
ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO											
APPLICATION AS FILED - PART I											
		(Column 1)		(Column 2)							
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)			
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A					
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))		N/A		N/A		N/A					
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A					
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 = *				x \$50 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 = *				x \$230 =					
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))											
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL					
APPLICATION AS AMENDED - PART II											
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT	03/21/2022	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 19	Minus	** 20	= 0			x \$50 =		0	
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0			x \$240 =		0	
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE		0	
		(Column 1)		(Column 2)		(Column 3)					
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	**	=			x \$0 =			
	Independent (37 CFR 1.16(h))	*	Minus	***	=			x \$0 =			
	☐ Application Size Fee (37 CFR 1.16(s))										
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
								TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.								LIE			
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".								/JEFFERY L OLSEN/			
*** 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.											

This collection of information is required by 37 CFR 1.16. 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, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Electronic Acknowledgement Receipt

EFS ID:	45276934
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	71212.4.8.6
Receipt Date:	21-MAR-2022
Filing Date:	21-JUN-2019
Time Stamp:	22:58:30
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Request for Reconsideration-After Non-Final Rejection	71212_4_8_6_OAresp.pdf	135338	no	7
			ab8dff2bc7031f1a66e17805a55811e7eb1e96e3		

Warnings:

Information:	
Total Files Size (in bytes):	135338
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.	

22859
Customer Number

PATENT
Attorney Docket No.: 71212.4.8.6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: F. Barry Bays
Application No.: 16/448,357 Group Art Unit: 3775
Filed: June 21, 2019 Examiner: BECCIA, Christopher J.
Title: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING
FULCRUM

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

AMENDMENT

Dear Commissioner:

In response to the Office Action mailed December 20, 2021, the period of response for which runs through March 21, 2022 (March 20th falling on a Sunday), please amend the application as follows.

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

Remarks begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A fulcrum for use in a bone realignment procedure comprising:
a body configured to be inserted in an intermetatarsal space between adjacent metatarsals,
and
a handle operatively connected to the body,
~~wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.~~
wherein the body has a first face and a second face on an opposite side from the first face,
the first face has surface features configured to inhibit proximal to distal movement of the
first face along a metatarsal against which the first face is positioned, and
the second face has surface features configured to inhibit dorsal to plantar movement of
the second face along a metatarsal against which the second face is positioned.
2. (Original) The fulcrum of claim 1, wherein the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion.
3. (Currently Amended) The fulcrum of claim 1, wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body, the body defines an axis extending along the length of the body, the handle defines a handle axis projecting at the non-zero degree angle from the body, and an angle between the axis of the body and the handle axis ranges from 20 degrees to 75 degrees.
4. (Original) The fulcrum of claim 3, wherein the angle ranges from 35 degrees to 55 degrees.

5. (Currently Amended) The fulcrum of claim 1, wherein
the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

the handle includes a grip portion and a handle body positioned between the body of the fulcrum and the grip portion;

the handle axis is defined by the handle body;

the grip portion defines a grip axis, and

an angle between the grip axis and the handle axis ranges from 20 degrees to 75 degrees.

6. (Original) The fulcrum of claim 5, wherein the grip axis is perpendicular to the axis defined by the body of the fulcrum.

7. (Original) The fulcrum of claim 1, wherein the body and the handle are formed as a unitary structure.

8. (Original) The fulcrum of claim 1, wherein the body is configured to be inserted between a first metatarsal and a second metatarsal.

9. (Withdrawn) The fulcrum of claim 1, wherein the body configured to be inserted in the intermetatarsal space is a first body, and the handle defines a second body also configured to be inserted in the intermetatarsal space, the first body and the second body varying in size.

10. (Withdrawn) The fulcrum of claim 9, wherein the first body has a maximum thickness, the second body has a maximum thickness, and the maximum thickness of the first body is less than the maximum thickness of the second body.

11. (Withdrawn) The fulcrum of claim 10, wherein
the first body extends from a leading end to a trailing end and the leading end of the first body is tapered, and
the second body extends from a leading end to a trailing end and the leading end of the second body is tapered.

12. (Canceled)
13. (Currently Amended) The fulcrum of claim [[12]] 1, wherein
the first face has multiple grooves extending lengthwise across the body, and
the second face has at least one of knurling and multiple grooves extending widthwise
across the body.
14. (Original) The fulcrum of claim 1, wherein the body is rectangular shaped.
15. (Original) The fulcrum of claim 14, wherein the body extends from a leading end to a
trailing end, the handle projects off the trailing end, and the leading end is tapered.
- 16–19. (Canceled)
20. (New) A system comprising:
a plurality of fulcrums each configured to be inserted into an intermetatarsal space
between adjacent metatarsals, wherein each of the plurality of fulcrums varies from each other of
the plurality of fulcrums by having at least one of a different size and a different shape;
wherein at least one of the plurality of fulcrums comprises a body configured to be
inserted in the intermetatarsal space between adjacent metatarsals and a handle operatively
connected to the body, wherein the body has a first face and a second face on an opposite side
from the first face, the first face has surface features configured to inhibit proximal to distal
movement of the first face along a metatarsal against which the first face is positioned, and the
second face has surface features configured to inhibit dorsal to plantar movement of the second
face along a metatarsal against which the second face is positioned.
21. (New) The system of claim 20, wherein the body is configured to be inserted between a
first metatarsal and a second metatarsal.
22. (New) The system of claim 20, wherein:

the first face has multiple grooves extending lengthwise across the body, and
the second face has at least one of knurling and multiple grooves extending widthwise
across the body.

23. (New) The system of claim 20, wherein the system comprises a sterile kit that further
includes a bone preparation guide.

24. (New) The system of claim 23, wherein the bone preparation guide comprises a first
guide slot configured to be positioned over a metatarsal to be cut and a second guide slot
configured to be positioned over a cuneiform to be cut, the first guide slot and the second guide
slot each being configured to guide a tissue removing instrument inserted therethrough.

REMARKS

This Amendment is responsive to the Office Action dated December 20, 2021. Applicant has amended claims 1, 3, 5, and 13, canceled claims 12 and 16–19, and added new claims 20–24. No new matter has been added by way of the amendments, and support for the amendments can be found throughout Applicant’s original disclosure including, e.g., at paragraphs [0081], [0121], and [0158]. Claims 1–11, 13–15, and 20–24 will be pending upon entry of this Amendment, with claims 9–11 withdrawn from consideration. Reconsideration of the application is respectfully requested.

Interview Summary

Applicant thanks the Examiner for his time and the courtesies extended during the telephonic interview conducted on March 18, 2022. Examiner Christopher Beccia and Applicant’s representative Paul J. LaVanway, Jr. (Reg. No. 64,610) were involved in the telephonic interview. The parties discussed claims 12 and 13 indicated allowable in the Office Action. No exhibits were introduced or discussed.

Applicant’s representative discussed potentially amending the features of claim 12 indicated allowable into independent claim 1 to proceed with compact examination of the application. Applicant’s representative also discussed removing limitations regarding the configuration of the handle in independent claim 1 if proceeding with this amendment, consistent with the amendments presented herein. The Examiner indicated that this type of amendment would appear to still be allowable, subject to any further typical search and examination needing to be conducted.

Claim Rejections Under 35 U.S.C. § 102(a)(1)

In the Office Action, previously-presented claims 1, 3, 4, 7, and 8 were rejected under 35 U.S.C. § 102(a)(1) as purportedly being anticipated by Davidson et al. (US 2009/0216089, hereinafter “Davidson”). In addition, previously-presented claims 2, 5, 6, 14 and 15 were rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Davidson in view of Brau et al. (US Pat. No. 6,416,465, hereinafter “Brau”).

While Applicant does not concede the propriety of the rejections, Applicant has amended the claims to proceed with the subject matter of dependent claim 12 indicated allowable. As discussed and agreed during the telephonic interview, this amendment overcomes the outstanding rejections. Accordingly, Applicant reserves further comment regarding the distinctions between the claims and the applied reference.

Double Patenting Rejections

In the Office Action, claims 1–8 and 12–15 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1–17 of U.S. Patent No. 10,939,939.

A Terminal Disclaimer accompanies this Amendment. The disclaimer is made to expedite issuance and is not intended as an admission that any claim of the present application is the same or an obvious variant of those of U.S. Patent No. US 10,939,939. This disclaimer obviates the double patenting rejection and places the claims in a condition for allowance.

CONCLUSION

It is submitted that all claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 06-1910. The Examiner is invited to telephone the undersigned attorney to discuss this application.

Dated: March 21, 2022

Respectfully submitted,

/Paul J. LaVanway, Jr./

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387
Facsimile: (612) 492-7077

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	16448357	
Filing Date	21-Jun-2019	
First Named Inventor	F. Bays	
Attorney Docket Number	71212.4.8.6	
Title of Invention	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
Treace Medical Concepts, Inc.	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 10939939 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.		

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☒ Small Entity ☐ Micro Entity ☐ Regular Undiscounted	
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.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>64610</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/Paul J. LaVanway, Jr./
Name	Paul LaVanway

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
 Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal

Application Number:	16448357			
Filing Date:	21-Jun-2019			
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM			
First Named Inventor/Applicant Name:	F. Barry Bays			
Filer:	Paul J. LaVanway Jr.			
Attorney Docket Number:	71212.4.8.6			
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	2814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				170

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16448357

Filing Date: 21-Jun-2019

Applicant/Patent under Reexamination: Bays

Electronic Terminal Disclaimer filed on March 21, 2022

☒ APPROVED

This patent is subject to a terminal disclaimer

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Electronic Acknowledgement Receipt

EFS ID:	45282263
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr.
Filer Authorized By:	
Attorney Docket Number:	71212.4.8.6
Receipt Date:	21-MAR-2022
Filing Date:	21-JUN-2019
Time Stamp:	23:03:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 170
RAM confirmation Number	E20223KN03420262
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	41241	no	2
			bb4118468eefbcea7c930daa1bb6ed34ecd3ae71		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	37842	no	2
			47ed1b4198c598b1043d5523d3e924ff06ba25f5		
Warnings:					
Information:					
Total Files Size (in bytes):			79083		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223
22859	7590	03/25/2022	EXAMINER	
FREDRIKSON & BYRON, P.A.			BECCIA, CHRISTOPHER J	
INTELLECTUAL PROPERTY GROUP			ART UNIT	PAPER NUMBER
200 SOUTH SIXTH STREET, SUITE 4000			3775	
MINNEAPOLIS, MN 55402			NOTIFICATION DATE	DELIVERY MODE
			03/25/2022	ELECTRONIC

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

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

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

IP@FREDLAW.COM

<i>Applicant-Initiated Interview Summary</i>	Application No. 16/448,357	Applicant(s) Bays et al.		
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775	AIA (First Inventor to File) Status Yes	Page 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	Title	Type
CHRISTOPHER J BECCIA	Primary Examiner	Telephonic
Paul LaVanway	Attorney of Record	

Date of Interview: 18 March 2022

Issues Discussed:

Other

Interview consisted of discussion regarding the indicated allowable subject matter of claims 12 and 13. It was agreed upon that the removal of the limitation of a handle operatively connected to the body as found in claim 1, would not affect the status indicating allowable subject matter of claims 12 and 13.

/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	
Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04 Please further see: MPEP 713.04 Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b) 37 CFR § 1.2 Business to be transacted in writing	

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



UNITED STATES PATENT AND TRADEMARK OFFICE

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

22859 7590 04/08/2022
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

EXAMINER

BECCIA, CHRISTOPHER J

ART UNIT

PAPER NUMBER

3775

DATE MAILED: 04/08/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223

TITLE OF INVENTION: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	07/08/2022

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

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

HOW TO REPLY TO THIS NOTICE:

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

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

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

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

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

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

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

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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

22859 7590 04/08/2022
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223

TITLE OF INVENTION: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	07/08/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
BECCIA, CHRISTOPHER J	3775	606-090000

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

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

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

2. For printing on the patent front page, list

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

1 _____

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

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

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

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

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

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

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

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

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223
22859	7590	04/08/2022	EXAMINER	
FREDRIKSON & BYRON, P.A. INTELLECTUAL PROPERTY GROUP 200 SOUTH SIXTH STREET, SUITE 4000 MINNEAPOLIS, MN 55402			BECCIA, CHRISTOPHER J	
			ART UNIT	PAPER NUMBER
			3775	

DATE MAILED: 04/08/2022

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

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

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

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

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

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

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

Privacy Act Statement

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

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

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

Notice of Allowability	Application No. 16/448,357	Applicant(s) Bays et al.	
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775	AIA (FITF) Status Yes

-- 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 Applicant Arguments/Remarks Made in an Amendment dated March 21, 2022.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on ____.

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

3. ☒ The allowed claim(s) is/are 1-11,13-15 and 20-24. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov**.

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

Certified copies:

a) ☐ All b) ☐ Some* c) ☐ None of the:

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

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

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

* Certified copies not received: ____.

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

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

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

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

Attachment(s)

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

/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	
---	--

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Election/Restrictions

Claim 1 is allowable. The restriction requirement, as set forth in the Office action mailed on August 20, 2021, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claims 9-11, directed to non-elected species are no longer withdrawn from consideration because the claim(s) requires all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: Most Pertinent prior art, including U.S. Patent Pub. No. 2009/0216089 to *Davidson* and U.S. Patent No. 6,416,465 to *Brau* disclose a fulcrum for use in a bone realignment procedure including a body that includes surface features

configured to be inserted in an intermetatarsal space between adjacent metatarsals, and a handle that includes a grip portion operatively connected to the body, wherein the handle projects at a non-zero degree angle from the body to define a tissue retraction space between the handle and the body.

The prior art fails to teach or disclose, however, the structural configuration wherein both the first face has surface features configured to inhibit proximal to distal movement of the first face along a metatarsal against which the first face is positioned, and the second face has surface features configured to inhibit dorsal to plantar movement of the second face along a metatarsal against which the second face is positioned.

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."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER J BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached Mon - Fri 8:30-5:00.

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

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Truong can be reached on 571-272-4705. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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

Art Unit: 3775

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

/CHRISTOPHER J BECCIA/
Primary Examiner, Art Unit 3775

Issue Classification 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

CPC						
Symbol					Type	Version
A61B	/	17	/	8866	F	2013-01-01
A61B	/	17	/	8061	I	2013-01-01
A61B	/	17	/	151	I	2013-01-01
A61B	/	2017	/	564	A	2013-01-01

CPC Combination Sets							
Symbol				Type	Set	Ranking	Version
	/		/				

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	26 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	39B

Issue Classification 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

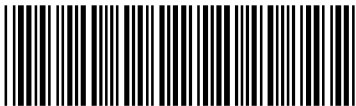
INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61B	/	17	/ 88

NON-CLAIMED			
/	/		

US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

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

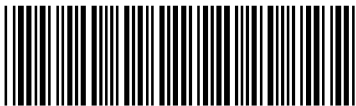
NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	19	
/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	26 March 2022	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	39B

Issue Classification 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

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

CLAIMS															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19										
	2		11		20										
	3		12		21										
	4		13		22										
	5		14		23										
	6		15		24										
	7		16												
	8		17												
	9		18												

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 19	
/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775 (Primary Examiner) _____ (Date) 26 March 2022		O.G. Print Claim(s) 1	O.G. Print Figure 39B

<i>Search Notes</i> 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

CPC - Searched*		
Symbol	Date	Examiner
A61B17/88, 8866, 80, 8061, 15, 1521	12/15/2021	CJB

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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

Search Notes		
Search Notes	Date	Examiner
Search History Attached	12/15/2021	CJB
Inventor Search	12/15/2021	CJB
Text Search	12/15/2021	CJB
Classification Search	12/15/2021	CJB
B/F Citations	12/15/2021	CJB
Search History Attached	03/26/2022	CJB

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	See Attached Search History	03/26/2022	CJB

/CHRISTOPHER J BECCIA/ Primary Examiner, Art Unit 3775	
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<i>Index of Claims</i> 	Application/Control No. 16/448,357	Applicant(s)/Patent Under Reexamination Bays et al.
	Examiner CHRISTOPHER J BECCIA	Art Unit 3775

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS										
☒ Claims renumbered in the same order as presented by applicant					☐ CPA		☒ T.D.		☐ R.1.47	
CLAIM		DATE								
Final	Original	08/16/2021	12/15/2021	03/26/2022						
	1	÷	✓	=						
	2	÷	✓	=						
	3	÷	✓	=						
	4	÷	✓	=						
	5	÷	✓	=						
	6	÷	✓	=						
	7	÷	✓	=						
	8	÷	✓	=						
	9	÷	N	=						
	10	÷	N	=						
	11	÷	N	=						
	12	÷	O	-						
	13	÷	O	=						
	14	÷	✓	=						
	15	÷	✓	=						
	16	÷	N	-						
	17	÷	N	-						
	18	÷	N	-						
	19	÷	N	-						
	20			=						
	21			=						
	22			=						
	23			=						
	24			=						

PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
L1	1	"15234226"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/09 04:54 PM
L2	102	rinner-james-a.in.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 08:27 AM
L4	1213	a61b17/88.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 08:27 AM
L5	855	a61b17/8863.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 08:27 AM
L6	31	("0275881" "20060259072" "20090222020" "20100268119" "20120047980" "20120247173" "20150012003" "2252891" "3244201" "3597775" "3626995" "3956950" "4005593" "4474046" "4488425" "5113685" "5490409" "5564302" "5572899" "5651283" "6644087" "7454939" "7473257" "7488331" "7740634" "8491601" "9186195" "9254158").PN. OR ("9427275").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 09:07 AM
L7	9	("3704620" "3747648" "4474046" "5490409" "5536270" "5819580" "6006581" "6325432").PN. OR ("8770006").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 09:08 AM
L8	16	("0275881" "4005593" "4474046" "4488425" "5113685" "5490409" "5564302" "5651283" "6644087" "7454939" "7473257" "7488331" "7740634").PN. OR ("8491601").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 09:08 AM
L9	3	"20140364860"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/09/17 09:30 AM
L10	15	("20020147450" "20040102777" "20070233111" "20100069973" "20110092981"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:30 AM

L11	6	"5564302" "5651283" "7189237" "8419745" "8439955" "8512385" "8518088" "8551107" "8758414" "8858562").PN. OR ("9918762").URPN. ("1047612" "20110107601" "20120247173" "2335028").PN. OR ("9872716").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L12	24	("1762234" "20060150699" "20120247173" "20140066994" "3447353" "3662580" "3785190" "4052879" "4428216" "4587824" "4608888" "4785650" "4986104" "5389099" "5431035" "5490409" "5548985" "6035691" "7234338" "7302887" "7454939" "9003859").PN. OR ("9421596").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L13	16	("0275881" "4005593" "4474046" "4488425" "5113685" "5490409" "5564302" "5651283" "6644087" "7454939" "7473257" "7488331" "7740634").PN. OR ("8491601").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L14	46	("0537550" "1824219" "2986194" "4474046").PN. OR ("5490409").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L15	32	("1108493" "1268922" "1842678" "3960147" "4038755" "4905679" "5217464" "5651283" "5951587" "6036692" "6960211").PN. OR ("7473257").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L16	52	("1054132" "2277204" "2339855" "2779382" "3018818" "3271990" "3918286" "4005593" "4446711" "4936131" "5237847" "5461897" "5490409" "5528921" "5548985" "5615572" "6035691").PN. OR ("6644087").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM

L17	42	("2525403" "2771116" "2892479" "3869917").PN. OR ("4005593").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:31 AM
L18	247	rod bender	(US-PGPUB; USPAT; USOCR)	ADJ	OFF	OFF	2018/09/17 11:33 AM
L19	1213	a61b17/88.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:33 AM
L20	34	L19 and fulcrum	(US-PGPUB; USPAT; USOCR)	ADJ	OFF	OFF	2018/09/17 11:33 AM
L21	855	a61b17/8863.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/09/17 11:33 AM
L22	78	L21 and fulcrum	(US-PGPUB; USPAT; USOCR)	ADJ	OFF	OFF	2018/09/17 11:33 AM
L23	877	a61b17/8863.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L24	248	L23 and post	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L25	362	L23 and pivot	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L26	239	L23 and lever	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L27	67	L23 and (lever with pivot)	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L28	11	("20090254090" "20110204120" "20130153631" "20130206815" "20140097228" "20140172024" "3960147" "4263903" "4592346" "5425490" "6533157").PN. OR ("10010320").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L29	44	("20040068187" "20040122549" "20050262911" "20060150699" "20070142751" "2961771" "3365804" "3433042" "3788116" "4249405" "4380922" "4403496" "4424699" "4848120" "5170654" "5207676" "5257184" "5301912" "5806521" "6035691" "6578280" "6701174" "6906724" "7017380" "7206626" "7454939" "7878038").PN. OR ("8549888").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:23 AM
L30	52	("20030199872" "20060074418"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:24 AM

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L31	9	("0690083" "3494233" "5988027" "6058820" "8127454").PN. OR ("8935974").URPN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:24 AM
L32	1263	a61b17/88.cpc.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:26 AM
L33	443	L32 and post	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:26 AM
L34	452	L32 and pivot	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:26 AM
L35	120	L32 and lever	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:26 AM
L36	19	L32 and (lever with pivot)	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:26 AM
L37	31	("0275881" "20060259072"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/01/16 10:27 AM

		"20090222020" "20100268119" "20120047980" "20120247173" "20150012003" "2252891" "3244201" "3597775" "3626995" "3956950" "4005593" "4474046" "4488425" "5113685" "5490409" "5564302" "5572899" "5651283" "6644087" "7454939" "7473257" "7488331" "7740634" "8491601" "9186195" "9254158").PN. OR ("9427275").URPN.					
L38	3	"16450795"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DK, EA, EE, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/08/04 09:23 PM
L39	4	"10327828".pn.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DK, EA, EE, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, RU, SU, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/08/04 09:24 PM
L40	2	("20120047980" "20140364860").pn. OR ("10327828").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:24 PM
L42	1519	a61b17/88.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:36 PM
L43	1149	a61b17/8863.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:36 PM
L44	1077	b21d7/06.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L45	708	b21d7/063.cpc.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L46	94	fulcrum WITH bender	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L47	46	("2525403" "2771116"	(US-PGPUB; USPAT;	OR	ON	ON	2021/08/04

L48	44	"2892479" "3869917").pn. OR ("4005593").urpn. AND (PGPB USPT USOC).dbnm. ("2502713" "3808867" "4077249" "4887447" "5113685" "5651283" "5819580" "6006581" "6035691" "6644087").pn. OR ("7454939").urpn. AND (PGPB USPT USOC).dbnm.	USOCR) (US-PGPUB; USPAT; USOCR)	OR	ON	ON	09:37 PM 2021/08/04 09:37 PM
L49	75	("1054132" "2277204" "2339855" "2779382" "3018818" "3271990" "3918286" "4005593" "4446711" "4936131" "5237847" "5461897" "5490409" "5528921" "5548985" "5615572" "6035691").pn. OR ("6644087").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L50	13	("3704620" "3747648" "4474046" "5490409" "5536270" "5819580" "6006581" "6325432").pn. OR ("8770006").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L51	26	("1762234" "3447353" "3662580" "3785190" "4052879" "4428216" "4587824" "4608888" "4785650" "4986104" "5389099" "5431035" "5490409" "5548985" "6035691" "7234338" "7302887" "7454939" "9003859" "20060150699" "20120247173" "20140066994").pn. OR ("9421596").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L52	29	("275881" "2252891" "3244201" "3597775" "3626995" "3956950" "4005593" "4474046" "4488425" "5113685" "5490409" "5564302"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM

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L53	18	("5564302" "5651283" "7189237" "8419745" "8439955" "8512385" "8518088" "8551107" "8758414" "8858562" "20020147450" "20040102777" "20070233111" "20100069973" "20110092981").pn. OR ("9918762").urpn. AND (PGPB USPT USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:37 PM
L54	28	L49 AND lever	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:38 PM
L55	19	L48 AND lever	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:38 PM
L56	35	L49 AND pivot	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:38 PM
L57	24	L48 AND pivot	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/08/04 09:38 PM
L58	11	(fulcrum bone realignment).clm.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	AND	ON	ON	2022/03/26 01:22 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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N38	0	(bending item pivot fulcrum lever).clm.	(USPAT)	AND	ON	ON	2019/01/16 10:27 AM
N39	45	(bending pivot fulcrum lever).clm.	(USPAT)	AND	ON	ON	2019/01/16 10:27 AM
N40	3	(bending pivot fulcrum lever post).clm.	(USPAT)	AND	ON	ON	2019/01/16 10:27 AM
N41	18	(bending pivot arm lever post).clm.	(USPAT)	AND	ON	ON	2021/11/29 08:26 AM
N42	7	(bending pivot arm lever post handle).clm.	(USPAT)	AND	ON	ON	2021/11/29 08:26 AM
N43	4	(fulcrum bone realignment).clm.	(US-PGPUB; USPAT)	AND	ON	ON	2022/03/26 01:22 PM
N44	4	(fulcrum bone realignment face).clm.	(US-PGPUB; USPAT)	AND	ON	ON	2022/03/26 01:22 PM

PART B - FEE(S) TRANSMITTAL

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

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

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

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

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

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

22859 7590 04/08/2022
FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

Certificate of Mailing or Transmission

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

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

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	6223

TITLE OF INVENTION: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	\$600	\$0.00	\$0.00	\$600	07/08/2022

EXAMINER	ART UNIT	CLASS-SUBCLASS
BECCIA, CHRISTOPHER J	3775	606-090000

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

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

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

2. For printing on the patent front page, list

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

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

1 Fredrikson & Byron, P.A.

2 _____

3 _____

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

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

(A) NAME OF ASSIGNEE

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

Treace Medical Concepts, Inc.

Ponte Vedra, Florida

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

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

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

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

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 06-1910

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

☐ Applicant certifying micro entity status. See 37 CFR 1.29

☐ Applicant asserting small entity status. See 37 CFR 1.27

☐ Applicant changing to regular undiscounted fee status.

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

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

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

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

Authorized Signature /Paul J. LaVanway, Jr./

Date July 8, 2022

Typed or printed name Paul J. LaVanway, Jr.

Registration No. 64610

Customer Number: 22859

Docket No.: 71212.4.8.6

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: F. Barry Bays
Application No.: 16/448,357 Group Art Unit: 3775
Filed: 06-21-2019 Examiner: BECCIA, CHRISTOPHER J
Title: TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM

COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Dear Commissioner:

Applicant has reviewed the Examiner's Statement of Reasons for Allowance accompanying the Notice of Allowance mailed April 8, 2022. Applicant does not acquiesce in any particular stated reasons for allowance or the characterization of the cited art.

Applicant agrees with the Examiner that the claims are allowable over the prior art. Applicant points out, however, that the claims require multiple limitations not taught or suggested by the prior art and that the claims are allowable for multiple reasons.

Applicant respectfully requests that the Examiner place the preceding comments into the prosecution record prior to issuance of the above-identified application. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Dated: July 8, 2022

Respectfully submitted,

FREDRIKSON & BYRON, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, MN 55402-1425 USA
Telephone: (612) 492-7387

/Paul J. LaVanway, Jr./

Paul J. LaVanway, Jr.
Registration No. 64,610

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 06-1910.

76160717 v1

Electronic Patent Application Fee Transmittal				
Application Number:		16448357		
Filing Date:		21-Jun-2019		
Title of Invention:		TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM		
First Named Inventor/Applicant Name:		F. Barry Bays		
Filer:		Paul J. LaVanway Jr./Tina Blissenbach		
Attorney Docket Number:		71212.4.8.6		
Filed as Small Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				600

Electronic Acknowledgement Receipt

EFS ID:	46142816
Application Number:	16448357
International Application Number:	
Confirmation Number:	6223
Title of Invention:	TARSAL-METATARSAL JOINT PROCEDURE UTILIZING FULCRUM
First Named Inventor/Applicant Name:	F. Barry Bays
Customer Number:	22859
Filer:	Paul J. LaVanway Jr./Tina Blissenbach
Filer Authorized By:	Paul J. LaVanway Jr.
Attorney Docket Number:	71212.4.8.6
Receipt Date:	08-JUL-2022
Filing Date:	21-JUN-2019
Time Stamp:	10:44:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$600
RAM confirmation Number	E202278A47163784
Deposit Account	
Authorized User	

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

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	71212-4-8-6-IF-Transmittal.pdf	1684382	no	1
			2895f2b21b27ba88ed4427c02ce319d43bed74c7		
Warnings:					
Information:					
2	Post Allowance Communication - Incoming	71212-4-8-6-Comments-on-Allowance.pdf	97043	no	1
			291a10b870b17aa24e85351a2dffacba944ec1b5		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	38172	no	2
			b205bb5c0cf5bdb99a715f1d29916bdc26d7a27e		
Warnings:					
Information:					
Total Files Size (in bytes):			1819597		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/448,357	08/16/2022	11413081	71212.4.8.6	6223

22859 7590 07/27/2022

FREDRIKSON & BYRON, P.A.
INTELLECTUAL PROPERTY GROUP
200 SOUTH SIXTH STREET, SUITE 4000
MINNEAPOLIS, MN 55402

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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

The Patent Term Adjustment is 420 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

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

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

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional inventors):

F. Barry Bays, Collierville, TN;
Robert D. Santrock, Morgantown, WV;
Paul Dayton, Fort Dodge, IA;
Daniel J. Hatch, Greeley, CO;
W. Bret Smith, Lexington, SC;

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Treace Medical Concepts, Inc., Ponte Vedra, FL;

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ACKNOWLEDGEMENT OF LOSS OF ENTITLEMENT TO ENTITY STATUS DISCOUNT

APPLICATION #	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET #	REQUEST ID
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	150856

The entity status change request below filed through Patent Center on 01/18/2024 has been accepted.

Certifications

APPLICANT CHANGING TO REGULAR UNDISCOUNTED FEE STATUS

Signature

I certify, in accordance with 37 CFR 1.4(d)(4), that I am one of the signatories making the entity status change.

Signature	Name	Registration #
/Paul J. LaVanway, Jr./	Paul LaVanway	64610



UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

ACKNOWLEDGEMENT OF CHANGE TO SMALL ENTITY STATUS

APPLICATION #	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET #	REQUEST ID
16/448,357	06/21/2019	F. Barry Bays	71212.4.8.6	364117

The entity status change request below filed through Patent Center on 03/04/2025 has been accepted.

Certifications

APPLICANT ASSERTING SMALL ENTITY STATUS. See 37CFR 1.27.

Signature

I certify, in accordance with 37 CFR 1.4(d)(4), that I am one of the signatories making the entity status change.

Signature	Name	Registration #
/Paul J. LaVanway, Jr./	Paul LaVanway	64610