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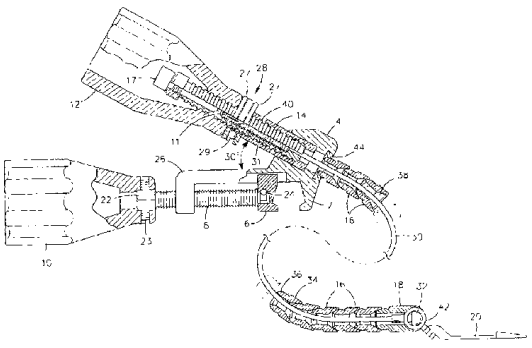
(54)【発明の名称】表面に対して物体を強制的に保持する可撓性のスタビライザーアーム

(57)【要約】
本発明は、必要な３次元的姿勢に位置することが出来、次いでその場所で凹凸のある表面に対して強制的に物体を保持する、可撓性スタビライザーアームアッセンブリーを提供する。一つの実施態様においては、本発明のアッセンブリーは、アームを静的固定物に取り付けるための取り付け基部、複数の関節で繋がれ隣接のリンクと回転可能に結合された細長いリンク、付属物を自由に回転出来る方法でアームの末端に取り付けるために適用されたアームの末端で自由に回転可能なターレット結合を含む。一度位置を決めると、取り付け基部に関してアームの姿勢を固定するために引き締め機構が動かされる。任意的に、付属物は、鼓動する心臓に対して、吸引体のような外科手術用具を保持するために適合された２又の足である。長さ１２インチまでの範囲の可撓性のアームは、固定位置を維持しつつ、末端に対して働く変動する２０ポンドまでの力に耐えることが出来る。これらの条件下でアームを安定化するために、アームは好ましくは、複数の関節で繋がれた細長いリンクと、１５０ポンドまでの反力に耐えるように、取り付け基部へのアームの摩



【特許請求の範囲】
【請求項１】
表面に対して物体を強制的に保持するスタビライザーアームアッセンブリーであって、
該スタビライザーアームアッセンブリーを静的固定物に取り外し可能に把持する為の、取り付け基部および移動可能な取り付けクランプを有する取り付けアッセンブリー
該取り付け基部に取り付けられた可撓性のアーム、ここで該可撓性のアームは関節で繋がれた細長い複数のリンクを有し、各リンクは隣のリンクと回転可能に連結されている、
アームの最も遠位端のリンクに取り付けられた自由に回転できるソケットを有するタレットジョイント、
該タレットジョイントに固定的に連結された保持付属物、および
該取り付け基部、アームの複数のリンク、およびタレットジョイントの自由に回転できるソケットを一緒にゆるく取り付ける締め付け機構
を有し、
ここで該締め付け機構の作動は、約１～約２０ポンドの反対圧力が該保持付属物に対してかけられながら、固定された姿勢で該アッセンブリーを保持するように、タレットジョイント、アームのリンク、および取り付け基部を互いに堅く押圧する、
ところのスタビライザーアームアッセンブリー。
【請求項２】
該物体が外科道具であり、該表面が脈動する心臓である特許請求の範囲第１項記載のスタビライザーアームアッセンブリー。
【請求項３】
表面が、研磨表面である特許請求の範囲第１項記載のスタビライザーアームアッセンブリー。
【請求項４】
スタビライザーアームアッセンブリーにおいて
取り付け基部、
その近位端において該取り付け基部に取り付けられている可撓性のアーム、ここで該可撓性のアームは、一定の若しくはその近位端から遠位端に段階的に減少する長さを有する複数の、関節で繋がれたリンクを有する、
該取り付け基部と該可撓性のアームの最も近位端のリンクとの間の継ぎ合わせにおける摩擦を高める継ぎ合わせ部材、
自由に回転できるソケットを介してアームの最も遠位端のリンクに取り付けられた、該自由に回転できるソケットを有するタレットジョイント、
該タレットジョイントに固定的に取り付けられた保持付属物、および
該取り付け基部、継ぎ合わせ部材、可撓性アームの複数のリンク、およびタレットジョイントの自由に回転できるソケットを一緒にゆるく取り付ける締め付け機構
を有し、
ここで該締め付け機構の作動は、約１～約２０ポンドの反対圧力が該付属物に対してかけられながら、固定された姿勢で該アッセンブリーを保持するように、タレットジョイント、アームのリンク、継ぎ合わせ部材、および取り付け基部を互いに堅く押圧し、および該継ぎ合わせ部材はアームの隣合うリンクの間の継ぎ合わせにおける力よりも大きな力に抗する、
ところのスタビライザーアームアッセンブリー。
【請求項５】
該力が、波打つ力である特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項６】
継ぎ合わせ部材における該力が約１～約１５０ポンドである特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項７】

該可撓性アームが、約２～約１２インチの長さである特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項８】
各リンクが、隣のリンクに回転可能に結合されている特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項９】
該リンクは実質的に円筒形のセグメントを有し、該セグメントは、該円筒の一端に取り付けられたノブ、およびアーム内の隣のリンクのノブを受けて該隣のリンクに回転可能に結合されるところの、該円筒の他端におけるソケットを有する、特許請求の範囲第８項記載のスタビライザーアームアッセンブリー。
【請求項１０】
ノブの表面の少なくとも一部が、ソケット内へのノブの摩擦フィットを増すように処理されている特許請求の範囲第９項記載のスタビライザーアームアッセンブリー。
【請求項１１】
該継ぎ合わせ部材が、最も近位端のリンクのノブを強制的に受ける為の、多面の、中心に位置された開口を有する板である特許請求の範囲第９項記載のスタビライザーアームアッセンブリー。
【請求項１２】
締め付け機構を作動すると取り付け基部内のソケット以内に最も近位端のリンクのノブの動きを制限する為に、該ぎ合わせ部材が取り付け基部内のスロット内に置かれる特許請求の範囲第１１項記載のスタビライザーアームアッセンブリー。
【請求項１３】
該継ぎ合わせ部材が、最も近位端のリンクのノブよりも硬い金属で構成されている特許請求の範囲第１２項記載のスタビライザーアームアッセンブリー。
【請求項１４】
該継ぎ合わせ部材が、再配置可能にスロット内に滑り込む特許請求の範囲第１３項記載のスタビライザーアームアッセンブリー。
【請求項１５】
該締め付け機構が、アームの遠位端と取り付け基部との間に接続されている特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項１６】
該締め付け機構が、締め付けケーブルに取り付けられた回転可能な締め付けスクリュウを有し、それによりスクリュウの回転が、アームとタレットジョイントの姿勢を固定するように締め付け機構を作動させる特許請求の範囲第１４項記載のスタビライザーアームアッセンブリー。
【請求項１７】
該複数のリンクの各々が中空の開口を含み、該ケーブルが該中空開口に通されて、取り付け基部とタレットジョイントとを連結する特許請求の範囲第１６項記載のスタビライザーアームアッセンブリー。
【請求項１８】
アームのたわみが、３６０度以下の弧を通る該アームに沿う曲線であり、締め付け機構の作動が該アームをそのような曲線姿勢に固定する特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項１９】
該継ぎ合わせ部材におけるアームのたわみが、取り付け基部の面に対し約２０～９０度である特許請求の範囲第１８項記載のスタビライザーアームアッセンブリー。
【請求項２０】
アームのたわみが三次元的である特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。
【請求項２１】

該締め付け機構が、遠位端において該ケーブルに、および近位端において、ケーブルの有効長さを短くする為にスクリュウを進める為の回転可能な再配置可能なハンドルに、取り付けられている締め付けスクリュウアッセンブリーを更に含み、それによって可撓性アームのリンクを互いに押圧する特許請求の範囲第２項記載のスタビライザーアームアッセンブリー。

【請求項２２】

該締め付けスクリュウアッセンブリーが、可撓性アームアッセンブリーがバラバラになる事を許さずに可撓性アーム内の各リンクを完全に露出するのに十分に、クリーニングの為に緩められる事が出来る特許請求の範囲第２０項記載のスタビライザーアームアッセンブリー。

【請求項２３】

取り付け基部が、該アッセンブリーを静的固定部に取り外し可能に取り付ける為の移動可能なクランプを有する特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項２４】

該付属物が、物体を表面に対して保持する為の、歯を有する、又状の足である特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項２５】

該物体が、又状の足の歯を受ける為の窓を有する心臓吸引体である特許請求の範囲第２４項記載のスタビライザーアームアッセンブリー。

【請求項２６】

該付属物が、つかみ具、切り取り具、はさみ、または平らな刃である特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項２７】

該付属物が、該締め付け機構の作動の前に該タレットジョイントとの継ぎ合わせにおいて自由に３６０度回転できる特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項２８】

該タレットジョイントとの継ぎ合わせにおけるたわみが、該締め付け機構の作動の前に１２０度以下の垂直方向角度である特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項２９】

タレットジョイントが、円筒の側部に半円形のスロット様の切り抜きを有する円筒状部材を有し、かつ該締め付け機構のケーブルが、その遠位端において、該半円形部材内で旋回するまたは回転するボールを有し、該ケーブルは該締め付け機構の作動の前にスロットに沿って移る特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項３０】

スタビライザーアームアッセンブリーがステンレススチールから構成されている特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項３１】

スタビライザーアームアッセンブリーが再使用の為に水蒸気で殺菌できる特許請求の範囲第４項記載のスタビライザーアームアッセンブリー。

【請求項３２】

スタビライザーアームアッセンブリーが、約１３２度Ｃの温度で１０分間、包装されないで水蒸気で殺菌できる特許請求の範囲第３１項記載のスタビライザーアームアッセンブリー。

【発明の詳細な説明】

【０００１】

【発明の属する技術分野】

本発明は一般的に、必要な形に固定する可撓性の保持部にかかる。より実用的には、本発

明は表面、特に凹凸のある表面に対して物体を強制的に保持するのに有用な可撓性の、関節で繋いだアームにかかる。

【０００２】

【従来の技術】

必要な位置或いは姿勢に調節出来、次いでそれを位置に「固定」する可撓性のアームは、産業や医療の種々な用途に便宜を与えている。例えば、そのような装置は、必要な角度や場所に照明を保持すること、或いは回転砥石に対して物体を保持することに有用である。しかし、実用的には、もしそれが重い物体を支持するとか、表面、特に凹凸のある表面に対して物体を強制的に保持するために使用される時は、可撓性のアームを位置に「固定」した後、動きから守ることは困難である。

【０００３】

箱の牽引機のような静的固定物の付属物として利用されれば、可撓性のアームは外科手術の間、医療器具を必要な場所に保持するのに使用できる。外科手術のために心臓の表面の或る領域を安定化するために、心臓の表面に十分な圧力を用いている間、凹凸があり拍動している心臓の表面に対する吸引体のような器具の位置を取り保持するために、このような方法で使用出来る可撓性のアームを得ることは、特に困難であると証明されて来た。凹凸のある表面の不断の動きは、アームの「固定」をこわし勝ちで、最終的に硬さの喪失や崩壊にさえ導く。

【０００４】

もし外科手術の位置が心臓の前の部分であれば（患者が彼の後ろに寝ている時）、心臓の前の部分に対して吸引器具を取り付け安定化するために、十分長いスタビライザーアームが必要である。しかし、関節で繋いだ可撓性の多数のリンクのアームにおいて、一度場所に置かれ位置に固定されると、アームが長い程アームを固く保持することが難しくなる。関節で繋いだアームにおける２つのリンクの各接合部は、動く可能性のある位置であり、静的固定物の上にアームを取り付けるために使用する基部に対する、最大の動きのモーメントは、可撓性のアームの接合部にある。この困難さは、アームがそれに対して置かれるべき表面が、拍動する心臓の表面のように、不断に動いている場合に組み合わされている。

【０００５】

【発明が解決しようとする課題】

従って本技術では、必要な形に固定される可撓性の保持のための部品類がなお必要である。より実用的には、本技術では、物体を表面、特に凹凸のある表面に対して、強制的に保持するのに有用な、可撓性の関節で繋いだアームがなお必要である。

【０００６】

【課題を解決するための手段】

本発明は，物体を表面に対して強制的保持するための、スタビライザーアームアッセンブリーを用意することにより、本技術における多くの問題を克服する。本発明のスタビライザーアームアッセンブリーは、取り付け基部およびスタビライザーアームアッセンブリーを静止固定物に取り外し可能に把持するための移動可能な取り付けクランプを含む取り付けアッセンブリー、取り付け基部に取り付けられた可撓性アーム、アームの最末端のリンクに取り付けられた自由に回転可能なソケットを含むターレット結合、固定的にターレット結合に取り付けられた保持付加物、およびアームの複数のリンク、および自由に回転可能なターレット結合のソケットと共に取り付け基部に緩やかに取り付けられた引き締め機構を含む。引き締め機構を動かすことにより、ターレット結合、アームのリンクおよび取り付け基部は、アッセンブリーは固定姿勢を保持するように硬く共に圧縮され、その間に約１ポンドないし約２０ポンドの反力が付加物に対してかかる。

【０００７】

他の実施の態様においては、本発明は取り付け基部、基部に近い末端で取り付け基部に取り付けられ基部からその末端へ徐々に長さの小さくなる複数の関節で繋いだリンクを含む可撓性アーム、取り付け基部と可撓性アームの最も基部に近いリンクの間の結合の摩擦を

強化する結合部品、アームの最も末端のリンクに自由に回転可能なソケットを経て取り付けられた自由に回転可能なソケットを含むターレット結合、ターレット結合に固定的に取り付けられた付加物、および取り付け基部に結合部品、可撓性アームのリンクの複数と共に緩やかに取り付けられた引き締め機構を含むスタビライザーアームアッセンブリーを用意する。引き締め機構の動きは、アッセンブリーが固定姿勢に保持されるように、ターレット接合、アームのリンク、結合部品、および取り付け基部を共に圧縮する。その間１ポンドないし２０ポンドの反力が付加物に対してかかり、そこで結合部品がアームの隣接リンクとの間の結合におけるよりも大きい力に抵抗する。

【０００８】

本発明によれば、凹凸のある表面に対して強制的に物体を保持するスタビライザーアームアッセンブリーが用意されている。一つの実施態様においては、本発明のスタビライザーアームアッセンブリーは、取り付け基部およびスタビライザーアームアッセンブリーを静止固定物に取り外し可能に把持するための移動可能な取り付けクランプを含む取り付けアッセンブリー、取り付け基部に取り付けられた可撓性アーム、アームの最末端のリンクに取り付けられた自由に回転可能なソケットを含むターレット結合、固定的にターレット結合に取り付けられた保持付加物、およびアームの複数のリンク、および自由に回転可能なターレット結合のソケットと共に取り付け基部に緩やかに取り付けられた引き締め機構を含む。可撓性アームは、隣接のリンクと回転可能に結合されている各リンクと共に、複数の関節で繋いだ延長リンクを含む。引き締め機構を動かすことにより、ターレット結合、アームのリンクおよび取り付け基部は、アッセンブリーが固定姿勢を保持するように硬く共に圧縮され、他方約１ポンドないし約２０ポンドの反力が付加物に対してかかる。

【０００９】

他の実施の態様においては、本発明は取り付け基部、基部に近い末端で取り付け基部に取り付けられ基部から均一な、或いはその末端へ徐々に長さの小さくなる複数の関節で繋いだリンクを含む可撓性アーム、取り付け基部と可撓性アームの最も基部に近いリンクの間の結合の摩擦を強化する結合部品、アームの最も末端のリンクに自由に回転可能なソケットを経て取り付けられた自由に回転可能なソケットを含むターレット結合、ターレット結合に固定的に取り付けられた付加物、および取り付け基部に結合部品、可撓性アームのリンクの複数と共に緩やかに取り付けられた引き締め機構を含むスタビライザーアームアッセンブリーを用意する。可撓性アームは、隣接のリンクと回転可能に結合されている各リンクと共に、複数の関節で繋いだ延長リンクを含む。引き締め機構の動きは、アッセンブリーが固定姿勢に保持されるように、ターレット接合、アームのリンク、結合部品、および取り付け基部を共に硬く圧縮する。その間１ポンドないし２０ポンドの反力が付加物に対してかかり、そこで結合部品がアームの隣接リンクとの間の結合におけるよりも大きい力に抵抗する。例えば、結合部品における力は約１ポンドから約１５０ポンドに出来る。

【００１０】

１つの実施態様において、引き締め機構は、ケーブル内の張力を増すためにケーブルに取り付けられた、引き締めスクリューを前に進めることにより動かされる。それによって、アームのリンクを共に強制し、リンク相互の動きを制限する。このように、引き締め機構の引き締めは、複数のリンクを必要な位置に固定する。アームを破壊することなく硬く用意するために、十分な張力をリンクに働かせるためには、ケーブルは３００シリーズ腐食抵抗ステンレス鋼のような、約５００ポンド力ないし１０００ポンド力の範囲の破壊強度（高い張力に耐えるために）を持つことが好ましい。

【００１１】

発明の可撓性アームアッセンブリーの好ましい実施態様は、図１～５を引用して記述する。図１に示すように、可撓性アームアッセンブリー２は、球状カップリング１８および付加物２０が取り付けられた付加物コネクター４２（図５及び図６に詳細に示される）を含むターレット結合５０の末端で終わる複数のリンク１６を持つ可撓性アーム３を含む。球状カップリング１８と、付加物コネクター４２の組合せはターレット結合５０を形成する。可撓性アーム３は、取り付け基部４の末端に取り付けられている。引き締め把手１２も

また取り付け基部４に、スラストベアリング２２およびスライド可能なコネクター１４内部の取り付け基部４の中の内腔に受け止められている制御スクリュー１７を経由して、取り付けられている。取り付け基部４はさらに、クランプの足７、移動可能なクランプの足６および動きを与えるスクリュー８を含む取り付け機構固定を含む。回転可能なクランプスクリュー把手１０は、取り付けアッセンブリーを静的固定物を把持するために、固定クランプ７の足に向かって移動可能なクランプの足６を進めるために、回転される。

【００１２】

本発明の可撓性アームアッセンブリーにおける可撓性アームの可撓性は、より短い長さのセグメントを有することにより増加するが、セグメントが短いほど、強度は小さくなる（例えば、アームは固定した位置へのロックがより困難であり、または、遠位先端に力がかけられるとき、不安定になるであろう）。リンクの相対的長さおよび他の寸法は、アームを作るために使用される物質（例えば物質の重量）および意図される目的によって決定され得る。例えば、脈動する心臓の手術での使用を目的とする本発明デバイスにおけるアーム（これは、アームを正確に位置させるために高度の可撓性を必要とする）の場合、可撓性と強度との最適の組み合わせは、均一なサイズの複数のリンクを有する、例えば、３１６グレードのステンレス鋼で作られるとき、約２インチ～１２インチの総アーム長のために約０．５インチ以下の長さの複数のリンクを有することにより達成される。この構成の結果、可撓性アームに沿って均一な応力分布が得られる。すなわち、任意の特定のリンク上での過剰の摩耗が防止される。しかし、別の実施態様では、アームにおけるリンクが、その近位端から遠位端へ向かって徐々に短くなる長さを有し得る。例えば、アームの近位端から遠位端へ向かって徐々に短くなる長さを有する以下の組のリンクで構成される可撓性アームも有用であることが分かった。すなわち、全長５．５インチの場合の、１インチの２つンリンク（もっとも近位に位置する）、３／４インチの２つのリンク、および１／２インチの４つのリンク（最も遠位に位置する）である。約１２インチ（３０ｃｍ）より長いときは、アームがたとえステンレス鋼で作られるとしても、１２ポンドもの大きい力が遠位先端（すなわち、付属物）に対してかけられると、アームを固定された位置に保持することが不可能であることが分かった。

【００１３】

好ましくは、アームの可撓性を高めるために、各リンクを、隣接するリンクに回転可能に連結する。例えば、図２の切断図に示すように、可撓性アームのリンク１６は、実質的に円筒形のセグメント３４を含み、リンクの円筒形セグメントの一端にノブ３６を有し、かつリンクの円筒形セグメントの反対の端部にあるくぼみに凹状ソケット３８を有する。円筒形リンクの一端のノブは、可撓性アームが緩められたままであるとき、隣接するリンクに回転可能に連結するように、隣接するリンクの端部のくぼみに設けられたソケットに収容される。しかし、締め付け機構を締めることにより、使用前にアームの姿勢を固定することを望む場合は、２つの隣接するリンクの各継ぎ目が運動可能性部位である。締め付け機構の作動後にアームの安定化を助けるために、ノブ３６の表面の少なくとも一部を処理して、ソケットへのノブの摩擦フィットを高めることができる。例えば、リンクの端部のノブの表面を摩擦誘導物質でコーティングすることができる。しかし、使用中に表面コーティングが腐食して、コーティングの薄片を生じる可能性がある。手術部位でスタビライザーアッセンブリーが使用されるべきならば、コーティングの薄片は望ましくない可能性がある。したがって、この状況では、隣接するリンクのソケットへのノブ３６の摩擦フィットを高めるために、可撓性アームのノブの表面の少なくとも一部を粗くすることが好ましい。例えば、金属ノブは、ノブを低速で回転させることにより細かいパターンの刻み目をつけて、ノブに溝パターンを刻むことができる。

【００１４】

好ましくは、可撓性アームのリンクのノブは、リンクの円筒形部分に付着する、一般的に凸状（例えば、実質的に球状）の部分を有するが、ノブの頭部（リンクの円筒形部分から最も遠い部分）ではより平らである。リンクの円筒形部分におけるソケットは、凸状のノブを収容するために、対応する凹形状（例えば、半球状）を有し得る。アームのリンク間

のノブとソケットの継ぎ目故に、可撓性アームは、３次元で自由に変形可能であり、および／または、図２に示すように、所望により「Ｏ」または「Ｓ」形状をとり得る。換言すると、可撓性アームは、その長さに沿って３６０°までの湾曲を有することができ、そして、横向きの動作において、および垂直面において曲がり得る。

【００１５】

可撓性アームのセグメント（すなわち、リンク１６）は、意図される目的のために十分な硬度および強度を有する物質で作られ得る。可撓性アームの堅い取り付け基部への継ぎ目は、アームが、固定された位置にロックされ、かつ反対の力がアームの遠位先端に対して、例えば遠位先端に固定された付属物を介してかけられるとき、最も大きい力を受ける個所である。アームが正しい位置にロックされるときに強度および剛性をさらに付与するために、本発明の可撓性アームアッセンブリーは、可撓性アーム３の堅い取り付け基部４への継ぎ目に位置する連結部品４４をさらに含む。連結部品４４は、取りつけ基部４と最近位リンク１６との間の継ぎ目における摩擦を高めるように設計されている。好ましくは、連結部品は、硬化された金属（すなわち、最近位リンクを作るために使用されたものより硬い金属）で作られ、取り替え可能であるように位置される。例えば、上記したように、関節でつながったアームが、ノブとソケットとのアッセンブリーにおいて互いに連結した複数のリンクで構成されているならば、連結部品４４は、締め付け機構が作動すると最近位リンクのノブが強制的に押圧されるところの、多くの面を有する開口部４５を有するプレートまたはディスクから成り得る。好ましくは、連結部品における開口部４５は、開口部の周囲に尖った部分と谷の部分とを与えるように配置された二重六角形（ｄｏｕｂｌｅ　ｈｅｘ）であり、締め付けられたときに尖った部分が可撓性アームの最近位のリンクにはまるようになっている。この実施態様では、最近位のリンクの取り付け基部への継ぎ目は、約１～約１５０ポンドの力に耐えることができ、一方、連結部品は、取り付け基部に関するアームの運動を実質的に排除する。別の実施態様では、開口部が約６～約３０の面を有し得る。多くの面を有する開口部４５は、滑らかでかつ曲線からなる開口部よりも、開口部内でのノブの運動に対して大きい耐性を与える。

【００１６】

図３に示すように、連結部品４４は、取り付け基部４におけるスロットの切り込みに連結部品を取り替え可能に保持するための面取りされた縁を有するスロット４６中にスライドするプレートである。連結部品は、曲線からなるものよりも多くの面を有するので、取り付け基部内のソケット中のノブは、可撓性アームの残りにおける曲線からなるソケット中のノブよりも、連結部品によって運動が制限され、したがって、表面、例えば波状の表面に対して物体を保持するために本発明のアッセンブリーを使用する際、最大の力の瞬間に、そのアッセンブリーは高められた剛性が付与されるであろう。

【００１７】

また、図３に示すように、コネクター４２が、付属物２０（また状の足としてここに示す）の遠位端に永久的に取り付けられている。例えば、コネクター４２は、付属物２０に溶接され得る。図５および６に詳細にさらに示すように、締め付け機構が作動されるまで、付属物２０が可撓性アーム３に自由に回転可能である（すなわち、垂直面において曲がるとともに、可撓性アームの端部で自由に回転しまたはスピンする）ように取り付けられるように、タレットジョイント５０が、可撓性アーム３の遠位先端の球状カップリング１８および付属物コネクター４２によって形成される。球状カップリング１８は、アームの隣接するリンクの凹状のくぼみにフィットするノブ、円筒形の中央部分、および付属物コネクター４２の円筒形状部分５６を収容するための半球状のソケット５４を有する遠位部分を含む。コネクター４２は、ケーブルのボールを収容する大きさの内部ボアを有する円筒形状部分を含み、円筒形の側面の周りに半円周的に延びるスロット様切り込み４８を有し、これは内部ボアとつながる開口部を付与する。追加の切り込み５２は、スロット様切り込み４８に対して直角をなし、ボール３２が円筒形コネクター４２のボアに収容されながらケーブルを切り込み５２を通ってスライドさせる大きさを有する。

ケーブル３０の遠位端のボール３２（図２に示す）は、好ましくは、ケーブル３０の端部

上にスエージング加工されたボール／シャンク管継手である。ボール３２は、ケーブルが、スロット様の切り込み４８に沿って移動し、付属物を反らせる（足のくるぶし関節のように）、例えば、ここに示すように約１２０°まで反らせる間、球状カップリング１８の半球状ソケット５４の側面によってピボットジョイント５０内に保持され、円筒形コネクター４２のボア内で３６０°ピボットしまたは回転する。したがって、付属物は、ピボットジョイント内で自由に回転可能であり、そしてアームおよびタレットジョイントが締め付け機構の作動によって固定された姿勢にロックされるまで表面の輪郭に対して付属物を正しく位置させるのを容易にするべく、広範囲の曲げを有する。ボール３２は、コネクター４２のスロットから遠くへ力を移動させ広げるために、シャンクに近い表面上に平たい部分を置くことにより改変され得る。

【００１８】

締め付け機構は、アームの遠位部分およびスタビライザーアッセンブリーの近位端（例えば、取り付け基部）を互いに連結し、可撓性アームのリンクを固定された姿勢にロックする。締め付けの前は、アッセンブリーの種々の部分の間の連結が、ケーブルによってゆるく結合している。ケーブルは、取り付け基部４、可撓性アームの複数のリンク１６、およびタレットジョイント５０の自由に回転できるソケットをケーブル３０およびボール３２を介して互いに連結している。締め付け機構が作動すると、約１～約２０ポンド、例えば約５～約１２ポンドの反対力が保持付属物に対してかけられながら、アッセンブリーを固定された姿勢で保持するように、タレットジョイント、アームのリンクおよび取り付け基部が互いに堅く押圧される。

【００１９】

特に、図３の拡大図に示されるように、締め付け機構は、（遠位端から近位端へ）制御スクリュ１７、牽引棒４０、内部の安全スクリュ１１（これは、ケーブル３０の外側にねじ切りされスエージング加工された部分３１の最近位端に沿って内部ねじ山にねじ込む）を有するケーブル３０およびケーブルボール３２を含み、ボール３２は、ケーブル３０の遠位端に固定して取り付けられている。牽引棒４０の近位部分は一般に、内部ボアおよび外部ねじ山を有する円筒形であり、外部ねじ山は、ハンドル１２内の内部ボアに沿った内部ねじ山とかみ合う。しかし、牽引棒４０の遠位部分は、平らな面を有し、内部ボアは、ケーブル３０のねじ切りされスエージング加工された部分３１上の外部ねじ山と噛み合う内部ねじ山がきられている。好ましくは、牽引棒上の外部ねじ山およびハンドル１２上の噛み合う内部ねじ山は、牽引棒４０のボアに沿った内部ねじ山およびケーブル３０のねじ切りされた部分３１に沿った、噛み合う外部のスエージング加工されたねじ山が削られる間、加えられる強度のためのアクネねじである。

【００２０】

アッセンブリーが図１に示すように組立てられるとき、滑り可能なコネクター１４は、引張棒４０、ハンドル１２、及び、ケーブルアッセンブリーが中に通され、且つ、付属物が取り付けられた可撓性のアームを結合するために使用される。滑り可能なコネクター１４は、円筒状の外側部分と、引張棒４０の遠位端（平らな側面を有する）を受け入れるようにデザインされ、該遠位端の側面と合うように平坦にされた側面を有する内側の孔部分を備えた遠位端を有する。滑り可能なコネクター１４の円筒状の外側部分は、取り付け基部４を通る穴（ボアホール）に滑り入るようなサイズにされる。滑り可能なコネクター１４は、滑らかな内側の穴と、四角い外側とを備えた近位端をも有し、遠位座金１７の外側と同一平面になるようなサイズにされる。中を通るケーブル３０の近位部分は、座金２７を通ってコネクター１４の内部の滑らかな穴を通過させられ、及び、軸受け２８及びハンドル１２の穴を刺し通される。引張棒４０は、ハンドル１２の近位端の大きい開口を通過させられ、その外側上に設けられたねじを介して、ハンドル１２の穴の内側ねじにねじ入れられる。スラスト軸受け２８は、２つの座金と１組の鋼製軸受け２９の３部品アッセンブリーであり、それは僅かに圧縮可能な物質、例えばナイロン、により覆われる。スラスト軸受け２８は、該アッセンブリーの種々の部分が、ケーブルが事実上短くなることによって（即ち、ケーブル３０のねじが切られた部分３１が引張棒内を近位に進行することによ

って）圧縮される際に、締め付けハンドル１２の回転を容易にする。スラスト軸受け２８は、締め付け機構が締め付けられて、該アッセンブリーが耐え得るのよりも大きな張力が突然施与されるのを防ぐために、いくらか圧縮する。

【００２１】

ハンドル１２が回転させられると、ハンドルが引張棒に沿って遠位に進行しながら、ケーブルのねじが切られた部分はハンドルに近づくように近位に進行する。安全ねじ１１はケーブルのねじが切られた部分の近位端の内側ねじに入れられ、引張棒４０の近位端の窪み中にぴったり合い、及び、引張棒の内部の穴と同じサイズを有し、引張棒内部の穴の内径を僅かに減じることにより該穴の中に形成されたショルダーに留まる。このようにして、安全ねじ１１（それは、長いハンドルを有するアレンレンチを用いてハンドル１２の近位の開口を通って施与されて、ケーブルアッセンブリーの端部に挿入される）は、ケーブルが引張棒から外に完全に抜け出ることを防止する働きをする。制御ねじ１７は、最後に挿入されて、アレンレンチを受け入れるための六角形のヘッドを有し、及び、引張棒の近位端の内側のねじにねじ入れられる。制御ねじ１７は、アッセンブリーのアライメントを保ち、及び、ケーブルが引張棒のなかに深く入りこみ過ぎるのを防止する働きをする。

【００２２】

ケーブル３０は、本発明の可撓性のアームアッセンブリーに、約２０ポンドまでの反対圧力がその先端に対して（例えば、その先端に取り付けられた付属物に対して、又は、波打った平面に対して付属物によって固定された装置に対して）施与されたときに、剛直に維持される能力を付与するのに十分な引張強度を有する任意の物質から作ることができる。例えば、破壊強度レーティング９２０ポンドを有する３００台耐腐食性ステンレス鋼ワイヤロープケーブルは、約９インチ長さの可撓性のアームに必要とされる強度を与えることが見出された。

【００２３】

スタビライザーアッセンブリアームに取り付けられるべき付属物は、特定の用途に適合された任意の形状、例えばつかみ具（グラッバー）、切り取り具（クリッパー）、はさみ、平らな刃（ブレード）等、であることができる。本明細書に示す好ましい実施態様において、付属物２０は、二つの歯を有する二股の脚（ｆｏｏｔ）である。この実施態様において、二つの歯を有するスタビライザー脚は、例えば１９９９年４月１６日出願の同時継続中の米国特許出願番号第０９／２９３，３３４、（引用により本明細書の包含される）に記載された可撓性の吸引体内に位置される付属物部分を通されるような形状にされる。本実施態様において、スタビライザーアームアッセンブリーは、吻合を行うためのオフポンプ冠状動脈バイパス（ＯＰＣＡＢ）処置の間、脈動している心臓の波打った表面に対して吸引体を保持するように適合される。好ましくは、本発明のスタビライザーアームアッセンブリーは、脈動する心臓の動脈側の波打った表面での使用に適合され及び適した大きさを有する。

【００２４】

図１～３に示すように、スタビライザーアームアッセンブリーの取り付け基部４は、スタビライザーアームアッセンブリーを静的固定物に取り外し可能に取り付けるための、回転可能なクランプねじにより駆動されるクランプを有する。図２の断面図に示すように、クランプ機構は、回転可能なクランプハンドル１０を回転することにより駆動され、該ハンドルはクランプねじ８の多面ヘッド２２と合うようになっており、可動クランプ台足６を固定クランプ台足７へと進める。セットねじ２３は、ヘッド２２の相対する面と接し、及び、所望であれば殺菌のためにクランプハンドル１０を取り外すために、取り外すことができる。セットピン２４は、可動クランプ台足６の窪みに収められており、且つ、クランプねじ８の遠位端を取り巻く溝に掛かり、クランプねじ８が回転されるにつれて、可動台足６を固定台足７へと強制的に進める。他の実施態様において、クランプ締め付けハンドル及び締め付けハンドルとして複数のハンドル又は交換可能なもしくは単一のハンドルを使用することができる。本実施態様において、引張棒にハンドルを取り付けるのにナットが使用され、該ナットは、引張棒が回転することなく締め付けハンドルが回転させられる

と引張棒上を動く。ハンドル内の穴は、クランプねじのヘッドに合うような大きさにもされる。本実施態様において、ハンドルは、操作をした後にアッセンブリー使用中の利便性のために、アッセンブリーから取り外されるようにして使用することも容易にできる。

【００２５】

ハンドルは、アッセンブリーの使用を妨害しないような任意の便宜な大きさにすることができる。例えば、本発明のアッセンブリーが外科手術で使用される場合には、外科医にとってはハンドルが約３インチの長さで、且つ、断面の最大直径が約２インチから約３インチであると、可撓性のアームを処置部の所望の位置に置く、例えば吸引体を脈動する心臓の表面上に強制的に保持するのに、便利である。過度の重さを回避するために、ハンドルは部分的に空洞であることができ、及び、プラスチック又はベークライト等から射出成形により作ることができる。あるいは、ハンドルは金属またはプラスチック等から公知の方法で機械加工により作ることができる。好ましい態様において、締め付けハンドル１２は、デルリン（Ｄｅｌｒｉｎ）５００プラスチックから射出成形され、及び、使用の間の利便性のために、取り付け部分の取り付け基部４正面に対して約０°～約９０°の角度、例えば約３０°～約４５°の角度で置かれる。本実施態様において、取り付けクランプは、好ましくは、多くの成人の心臓開創器と共に使用できる（コンパティブルな）大きさを有する。例えば、クランプは約０．８インチ（２ｃｍ）幅であり、及び、厚み０．１２５インチ（０．３２ｃｍ）～０．４インチ（１．０２ｃｍ）で幅０．２５インチ～１．５インチ（３．８１ｃｍ）の長方形部分を収容する。

【００２６】

本発明のスタビライザーアッセンブリーにおける可撓性のアームは、３次元方向に、例えば手動で操作可能であり、所望の形状となり、そして、締め付け機構が駆動されたときに存在する任意の状態で固定される。しかし、一旦、所望の位置に固定されると、アームはその長さ方向及び最大応力点、即ち、アームと取り付け基部との接合部、の双方において実質的に剛直になる。これらの特徴は、本発明のデバイスを、タレットジョイントに取り付けられた付属物（又は付属物に取り付けられた、もしくは付属物に保持された物体）を任意の波打った表面に対して保持するのに、特に適したものとする。例えば、本発明のスタビライザーアッセンブリーの好ましい用途は、吸引デバイスを脈動する心臓に対して動かないように強制的に保持して外科手術のために該部位を安定化することである。他の実施態様において、本発明のデバイスは、研磨処理の間に、研磨回転板に対して対象物を保持すること等に使用することができる。

【００２７】

本発明をより詳細に説明するために、可撓性のアームアッセンブリーを、以下の物質から作った：可撓性のアームのリンク１６、付属物２０及び引張棒４０を３１６ステンレス鋼から作った；継ぎ合わせ部材４４を焼き入れされた１７－４ステンレス鋼から作った；ケーブル３０を３００台耐腐食性ステンレス鋼から作った；セットねじ、セットピン及び安全ねじを１８－８ステンレス鋼から作り、及び、他の（ハンドル及びスラスト軸受けの軸受けハウジングを除く）総ての部品を１８－８ステンレス鋼から作った。しかし、本発明の可撓性のアームアッセンブリーを機械加工することを所望する場合には、種々の耐腐食性、焼き入れ金属物質、例えばステンレス鋼、チタン等、を使うことができる。あるいは、同等の強度及び硬さのプラスチック又は複合材料も、又、アッセンブリーの種々の部品を公知の方法、例えば射出成形、で作るために使用することができる。

【００２８】

好ましい実施態様において、可撓性のアームアッセンブリーは、（例えば医療用途において）繰り返し使用するようにデザインされ、従って、再使用のために殺菌されるよう容易に適合される。殺菌を容易にするために、ケーブルがリンクの間に見えるまで部分的にケーブルを引張棒の外に引き出し、及び、コネクター１４が取り付け基部から滑り出るように、締め付けハンドルを回転することにより、締め付けアッセンブリーを緩めることができる。安全ねじは、装置がばらばらになるまでケーブルが出てしまうことを防止する。この、緩められた状態で、アッセンブリーは、リンクの間に存在し得るくずを容易に洗浄し

て取り除くことができる。さらに、アッセンブリーが焼き入れされた金属から作られる実施態様の場合、アッセンブリー全体を殺菌することができる。例えば、本明細書に記載された好ましい態様では、アッセンブリーは包まれていない状態で１３２℃で、約１０分間、自然空気置換装置（ｇｒａｖｉｔｙ　ａｉｒ　ｄｉｓｐｌａｃｅｍｅｎｔ）内でスチーム殺菌することができる。二重に包まれた装置（殺菌用品包装用の使い捨てリントフリー不織布を用いて二重包装）については、好適なスチーム洗浄温度は１２１℃で３０分間である。本明細書に記載されたように適切に注意すれば、本発明の可撓性のアームは、複数回、例えば約５００～１０００回、再利用できる（例えば、締め付けられ、緩められ、及び殺菌される）。

【００２９】

本発明の可撓性アームアッセンブリーは、使用し易くするために、例えば水溶性潤滑剤中に３０秒間、完全に漬けることによって、滑りをよくすることができる。適する潤滑剤は、例えば、ＰＲＥＳＥＲＶＥ（商標）インストルメントマイルド（ジョンソン　＆　ジョンソン－コッドマン社、
カタログ　Ｎｏ．４３３－１０３３）でスチーム加圧滅菌（オートクレーブ）されたときに金属表面に粘着する高粘度潤滑剤である。

【図面の簡単な説明】

【図１】固定姿勢に固定された、本発明のスタビライザーアームアッセンブリーを示す透視図である。

【図２】可撓性アームの中央軸に沿って作用する引き締め機構を示す断面図である。ケーブルアッセンブリーの末端において、末端に取り付けられたボールがターレット結合中に保持され、それに向けて付加物（足）が固定的に取り付けられている。把持ハンドルの断面は、取り外し可能に静的固定物に可撓性アームアッセンブリーを取り付けるのに使用される、把持スクリューの機構を示す。

【図３】本発明の可撓性アームアッセンブリーの好ましい実施態様を示す分解組立図である。

【図４】引き締め機構を動きによって固定姿勢に固定された本発明の可撓性アームを示す概要図である。位置決めおよび引き締め機構の動きの前の可撓性アームの位置は、ファントム（点線）で示している。

【図５】部分的断面によってターレット結合の中の円筒状コネクターの中に取り込まれたケーブルボールを示した等測投影図である。コネクターの外側に取り付けられた付加物は、ファントムで示している。

【図６】本発明の可撓性アームアッセンブリーを、ターレット結合の中に乗っているケーブルボールとターレット結合の外側に取り付けられた付加物を示す、末端の中央線に沿った断面図である。

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(54) Title: FLEXIBLE STABILIZER ARM FOR FORCIBLY HOLDING AN OBJECT AGAINST A SURFACE

(57) Abstract: The present invention provides a flexible stabilizer arm assembly that can be positioned in a desired three-dimensional attitude and then fixed in place to forceably holding an object against an undulating surface. In one embodiment, the invention assembly comprises a mounting base for attachment of the arm to a stationary fixture, a flexible arm of multiple articulated elongate links rotatably joined to adjacent links, a freely rotatable turret joint at the distal end of the arm that is adapted to attach an appendage in freely rotatable fashion to the distal end of the arm. Once positioned, a tightening mechanism is actuated to fix the attitude of the arm with respect to the mounting base. Optionally, the appendage is a two-tined foot adapted for holding a surgical instrument, such as a suction body, against a beating heart. The flexible arm, which ranges up to 12 inches in length, can withstand an undulating force exerted against the distal end of up to 20 pounds while remaining in the fixed position. To stabilize the arm under these conditions, the arm preferably comprises multiple articulated elongate links and a joining piece that substantially increases the friction fit of the arm to the mounting base so as to withstand a counter-force of up to 150 pounds.

FLEXIBLE STABILIZER ARM FOR FORCIBLY HOLDING AN OBJECT AGAINST A SURFACE

FIELD OF THE INVENTION

The present invention generally relates to flexible holding members that lock into a desired shape. More particularly, the present invention relates to flexible articulated arms useful for forceably holding an object against a surface, particularly an undulating surface.

BACKGROUND OF THE INVENTION

Flexible arms that can be adjusted to a desired position or attitude and then "locked" into position serve a variety of uses in industry and in medicine. For example, such devices are useful for holding a light at a desirable angle or location, or for holding an object against a grinding wheel. However, in practice it is difficult to keep the flexible arm from moving after it has been "locked" into position if it is used to hold or support a heavy object or when used to forceably hold an object against a surface, particularly against an undulating surface.

When adapted for attachment to a stationary object, such as a chest retractor, a flexible arm can be used during surgery for holding a medical device in a desired location. It has proven particularly difficult to obtain a flexible arm that can be used in this fashion to position and hold a device, such as a suction body, against the undulating surface of a beating heart while applying sufficient pressure to the surface of the heart to stabilize an area on the surface of the heart for surgery. The constant movement of the undulating surface tends to break down the "set" of the arm, leading to eventual loss of rigidity and even collapse.

If the surgical site is on the anterior side of the heart (when the patient is lying on his back), it would be desirable to have a stabilizer arm long enough to attach and stabilize the suction device against the anterior side of the heart. However, in an articulated flexible arm of multiple links, the longer the arm, the harder it is to keep the arm rigid once it is in place and locked into position. Each jointure between two links in the articulated arm is a potential site of movement, and the greatest moment of movement is at the jointure of the flexible arm to the base used to mount the arm upon a stationary object. This difficulty is compounded when the surface against which the arm is to be placed is in constant movement, such as the surface of a beating heart.

Accordingly, there is still a need in the art for flexible holding members that lock into a desired shape. More particularly, there is still a need in the art for flexible articulated arms useful for forceably holding an object against a surface, particularly an undulating surface.

BRIEF DESCRIPTION OF THE INVENTION

The present invention overcomes many of the problems in the art by providing stabilizer arm assemblies for forceably holding an object against a surface. The invention stabilizer arm assembly comprises a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture; a flexible arm attached to the mounting base, said flexible arm comprising multiple articulated elongate links with each link being rotatably joined to adjacent links; a turret joint comprising a freely rotatable socket attached to the distal-most link of the arm; a holding appendage fixedly joined to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly compressed together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage.

In another embodiment, the invention provides a stabilizer arm assembly comprising a mounting base; a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of graduated diminishing length from the proximal to the distal end thereof; a jointing piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm; a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket; an appendage fixedly attached to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the jointing piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint. Acutation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective drawing showing the invention stabilizer arm assembly locked into a fixed attitude.

Figure 2 is a cut-away drawing showing the tightening mechanism running down the central axis of the flexible arm. At the distal end of the cable assembly, a ball attached to the distal end of the cable is held within the turret joint, to which an appendage (foot) is fixedly attached. A cut-away of the clamping handle shows the mechanism of the clamping screw, which is used to removeably attach the flexible arm assembly to a stationary fixture.

Figure 3 is an exploded drawing showing a preferred embodiment of the invention flexible arm assembly.

Figure 4 is a schematic drawing showing the invention flexible arm locked into a fixed attitude by actuation of the tightening mechanism. The position of the flexible arm prior to positioning and actuation of the tightening mechanism is shown in phantom (dotted lines).

Figure 5 is an isometric drawing showing in partial cut-away the cable ball captured within the cylindrical connector in the turret joint. The appendage, which is is attached to the exterior of the connector is shown in phantom.

Figure 6 is a cut-away drawing down the median of the distal end of the invention flexible arm assembly showing the cable ball riding within the turret joint and the appendage attached to the exterior of the turret joint.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, there are provided stabilizer arm assemblies for forceably holding an object against an undulating surface. In one embodiment, the invention stabilizer arm assembly comprises a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture; a flexible arm attached to the mounting base; a turret joint comprising a freely rotatsble socket attached to the distal-most link of the arm; a holding appendage fixedly joined to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint. The flexible arm comprises multiple articulated elongate links with each link being rotatably joined to adjacent links. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly

compresses together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the holding appendage.

In another embodiment, the invention provides a stabilizer arm assembly comprising a mounting base; a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of uniform or graduated diminishing length from the proximal to the distal end thereof; a joining piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm; a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket; an appendage fixedly attached to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the joining piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint. The flexible arm comprises multiple articulated elongate links with each link being rotatably joined to adjacent links. Acutation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm. For example, the force at the joining piece can be from about one pound to about 150 pounds.

In one embodiment, the tightening mechanism is actuated by advancing a tightening screw attached to the cable to increase tension in the cable, thereby forcing the links of the arm together, restricting motion of the links relative to one another. Thus, tightening of the tightening mechanism locks the multiple links into the desired position. To exert sufficient tension on the links to provide rigidity to the arm without breaking, the cable preferably has a breaking strength (to withstand high tensile force) in the range from about 500 to 1000 pounds force, such as 300 series corrosion resistant stainless steel.

The preferred embodiments of the invention flexible arm assembly are described with reference to Figures 1-5. As shown in Figure 1, flexible arm assembly 2 comprises a flexible arm 3 having a plurality of links 16, ending at the distal tip in turret joint 50, which is comprised of spherical coupling 18 and appendage connector 42 (shown in detail in Figures 5 and 6), to which is attached appendage 20. The combination of spherical coupling 18 and appendage connector 42 forms turret joint 50. The flexible arm 3 is attached at the proximal end to mounting base 4. Tightening handle 12 is also attached to mounting base 4 via control screw 17, thrust bearing 22, and slideable connector 14, which is received into an internal bore within mounting base 4. Mounting base 4 further comprises a mounting mechanism comprising fixed clamp foot 7,

moveable clamp foot 6, and actuating clamp screw 8. Rotatable clamp screw handle 10 is rotated to advance moveable clamp foot 6 towards fixed clamp foot 7 to clamp the mounting assembly to a stationary fixture.

The flexibility of the flexible arm in the invention flexible arm assembly is increased by having segments of shorter length, but the shorter the segments, the less strength (e.g., the arm is more difficult to lock into a rigid position or will become unstable when a force is applied to the distal tip). The relative length and other dimensions of the links can be determined by the materials used to fabricate the arm (e.g., the weight of the materials), and the intended purpose. For example, it has been determined that, for an arm in an invention device intended for use in beating heart surgery (which requires a high degree of flexibility to position the arm accurately) the optimum combination of flexibility and strength is achieved by having multiple links of uniform size, for example about 0.5 inch in length or less for a total arm length of about 2 inches to 12 inches when fabricated of 316 grade stainless steel. This configuration results in uniform distribution of stress along the flexible arm, thus preventing excessive wear on any particular link. However, in another embodiment the links in the arm can have diminishing graduated length from the proximal to the distal end thereof. For example, a flexible arm comprised of the following set of links of graduated diminishing length from the proximal to the distal end of the arm has also proven useful: two links of one inch (located most proximally), two links of ¾ inch, and four links of ½ inch (located most distally), for a total of 5 ½ inches. At a length greater than about 12 inches (30 cm), even if the arm if fabricated of stainless steel, it has been found impossible to maintain the arm in a fixed position when a force as great as 12 pounds is applied against the distal tip (i.e., the appendage).

Preferably, to enhance flexibility of the arm, each link is rotatably joined to adjacent links. For example, as shown in cut-away in Figure 2, links 16 of the flexible arm comprise a substantially cylindrical segment 34, with knob 36 at one end of the cylindrical segment of the link and concave socket 38 recessed into the opposite end of the cylindrical segment of the link. The knob at one end of the cylindrical link is received into the socket recessed at the end of an adjacent link so as to rotatably join to the adjacent link when the flexible arm remains loosened. However, when it is desired to fix the attitude of the arm prior to use by tightening the tightening mechanism, each jointure of two adjacent links is a potential site of movement. To aid in stabilizing the arm upon actuation of the tightening mechanism, at least a portion of the surface of the knobs 36 can be treated to increase the friction fit of the knobs into the sockets. For example, the surfaces of the knobs at the end of the links can be coated with a friction-inducing substance. However, it is possible that a surface coating will erode during use, forming flakes of coating. If the stabilizer

assembly is to be used at a surgical site, the flakes of coating may be undesirable. Consequently, in this situation, it is preferred to roughen at least part of the surface of the knobs in the flexible arm to increase the friction fit of the knob 36 into the socket of the adjoining link. For example, metal knobs can be scored with a fine pattern by turning the knobs at low speed to cut a groove pattern in the knobs.

Preferably, the knobs of the links of the flexible arm have a generally convex (e.g., substantially spherical) portion that attaches to the cylindrical portion of the link, but are more flattened at the head of the knob (the portion most distant from the cylindrical portion of the link). The sockets in the cylindrical portion of the links can have a corresponding concave shape (e.g., semi-spherical) to receive the convex knobs. Due to the knob and socket jointures between the links of the arm, the flexible arm is freely deformable in three dimensions and/or can assume an "O" or "S" shape, if desired, as shown in Figure 2. In other words, the flexible arm can have up to 360° of curvature along its length and can flex in a sideways motion as well as in a vertical plane.

The segments (i.e., links 16) of the flexible arm can be manufactured of any substance having sufficient hardness and strength for the intended purpose. The jointure of the flexible arm to the rigid mounting base is the point that experiences the greatest force when the arm is locked into a fixed position and a counter-force is applied against the distal tip of the arm, e.g., via an appendage fixed at the distal tip. To further provide strength and rigidity when the arm is locked into position, the invention flexible arm assembly further comprises a joining piece 44 located at the jointure of the flexible arm 3 to the rigid mounting base 4. The joining piece 44 is designed to enhance friction in the jointure between the mounting base 4 and the proximal-most link 16. Preferably, the joining piece is made of hardened metal (i.e. a metal harder than that used to fabricate the proximal most link) and is positioned to be replaceable. For example, if the articulated arm is comprised of multiple links joined together in a knob and socket assembly, as described above, the joining piece 44 can consist of a plate or disc having a many-sided opening 45 into which the knob of the proximal-most link is forceably compressed upon actuation of the tightening mechanism. Preferably the opening 45 in the joining piece is a double hex arranged to provide points and valleys around the opening so that the points will dig into the proximal-most link of the flexible arm when tightened. In this embodiment, the jointure of the proximal-most link to the mounting base can withstand a force of from about one pound to about 150 pounds while the joining piece substantially eliminates movement of the arm with respect to the mounting base. In alternative embodiments the opening can have from about 6 to about 30 sides . The many-sided opening 45 provides a greater

resistance to movement of the knob within the opening than would a smooth and curvilinear opening.

As shown in Figure 3, the joining piece 44 is a plate that slides into a slot 46, which as beveled edges to replaceably hold the joining piece into the slot cut in mounting base 4. Because the joining piece is many-sided rather than curvilinear, the knob in the socket within the mounting base will be more restricted in movement by the joining piece than are the knobs in the curvilinear sockets in the balance of the flexible arm, thus providing enhanced rigidity to the invention assembly at the point of greatest force during use of the assembly to hold an object against a surface, such as an undulating surface.

As also shown in Figure 3, connector 42 is permanently attached to the proximal end of appendage 20 (shown here as a forked foot). For example, connector 42 can be welded to appendage 20. As further shown in detail in Figures 5 and 6, the turret joint 50 is formed by spherical coupling 18 at the distal tip of the flexible arm 3 and appendage connector 42 so a to attach appendage 20 to flexible arm 3 in a freely rotatable manner (i.e., to flex in a vertical plane as well as to freely rotate or spin at the end of the flexible arm) until the tightening mechanism is actuated. Spherical coupling 18 comprises a knob that fits into the concave recess of its adjoining link in the arm, a cylindrical middle portion, and a distal portion with semi-spherical socket 54 for receiving the cylindrical-shaped portion 56 of appendage connector 42. Connector 42 comprises a cylindrical-shaped portion with internal bore sized to receive the ball of the cable and which has a slot-like cut-out 48 running semi-circumferentially around the side of the cylinder, providing an opening that connects with the internal bore. An additional cut out 52 is at right angles to the slot-like cut-out 48 and is sized to allow the cable to slide through cut out 52 while ball 32 is received into the bore of cylindrical connector 42.

Ball 32 at the distal end of cable 30 (shown in Figure 2) is preferably a ball and shank fitting which is swaged onto the end of cable 30. Ball 32 is held within pivot joint 50 by the sides of the semi-spherical socket 54 in spherical coupling 18 and pivots or rotates 360° within the bore of the cylindrical connector 42 while the cable translates along slot-like cut-out 48, giving a deflection of the appendage (like a foot at an ankle joint), for example a deflection of up to about 120° as shown here. Thus the appendage is freely rotatable within the pivot joint and has a large range of flexure to facilitate accurate positioning of the appendage against any contour of a surface until the arm and turret joint is locked into a fixed attitude by actuation of the tightening mechanism. Ball 32 can be modified by placing a flat on the surface closes to the shank to move and spread the force away from the slot in connector 42.

The tightening mechanism connects together the distal portion of the arm and the proximal end of the stabilizer assembly (e.g., the mounting base) and locks the links of the flexible arm into a fixed attitude. Before tightening, the connection between the various parts of the assembly are loosely joined by the cable, which connects together mounting base 4, the plurality of links 16 of the flexible arm, and the freely rotatable socket of the turret joint 50 via cable 30 and ball 32. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly compressed together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds, for example from about five to about twelve pounds, of counter-force is applied against the holding appendage.

More particularly, as shown in exploded view in Figure 3, the tightening mechanism comprises (from proximal to distal end) control screw 17, draw bar 40, cable 30 with internal, security screw 11 (that screws into internal threads along the proximal-most end of exteriorly threaded and swaged portion 31 of cable 30) and cable ball 32, which is fixedly attached at the distal end of cable 30. The proximal portion of draw bar 40 is generally cylindrical with an interior bore and external threads that mate with internal threads along an internal bore within handle 12. However, the distal portion of draw bar 40 has flatted sides and the interior bore is lined with internal threads that mate with the external threads on the threaded and swaged portion 31 of cable 30. Preferably, the external threads on the draw bar and the mating internal threads on handle 12 are acme threads for added strength while the internal threads along the bore of draw bar 40 and the mating external, swaged threads along the threaded portion 31 of cable 30 are pointed.

When the assembly is assembled as shown in Figure 1, slideable connector 14 is used to join together draw bar 40, handle 12 and the flexible arm threaded through with the cable assembly and attached appendage. Slideable connector 14 has a distal end with a cylindrical exterior portion and an interior bore with flatted sides designed to receive the distal end (with mating flatted sides) of draw bar 40. The cylindrical exterior portion of connector 14 is sized to slide into a bore hole through mounting base 4. Slideable connector 14 also comprises a proximal portion with a smooth interior bore and squared exterior sized to sit flush against the exterior of distal washer 17. The proximal, threaded portion of cable 30 is passed through an interior smooth bore in connector 14 through washers 27 and thrust bearing 28 and the bore of handle 12. Draw bar 40 passes through the large opening the in proximal end of handle 12 and is threaded via the exterior threads thereon into the mating interior threads in the bore of handle 12 . The thrust bearing 28 is a three piece assembly of two washers 27 and a set of steel bearings

29, which are encased in a slightly compressible material , such as nylon. Thrust bearing 28 facilitates rotation of the tightening handle 12 as the various parts of the assembly are compressed together by effective shortening of the cable (i.e., by advancement of the threaded portion 31 of cable 30 proximally within the draw bar). Thrust bearing 28 compresses somewhat as the tightening mechanism is tightened to prevent sudden application of greater tensile force than can be tolerated by the assembly.

When handle 12 is rotated, the threaded portion of the cable advances proximally up the handle, while the handle advances distally along the draw bar. Security screw 11, which screws into the interior threads at the proximal end of the threaded portion of the cable, also fits into a recess in the proximal end of draw bar 40 and is sized with respect to the interior bore of the draw bar to lodge against shoulders therein created by a small decrease in the internal diameter of the interior bore in the draw bar. Thus, security screw 11, which is inserted into the end of the cable assembly using a long handled Allen wrench applied through the proximal opening of handle 12, functions to prevent backthreading of the cable completely out of the draw bar. Control screw 17, which is inserted last, has a hex head for receiving an Allen wrench and screws into the interior threads at the proximal end of the draw bar. Control screw 17 functions to keep alignment of the assembly and to prevent threading of the cable too far into the draw bar.

Cable 30 can be manufactured of any substance having sufficient tensile strength to provide the invention flexible arm assembly with the capability to remain rigid when up to about twenty pounds of counter-force is applied against its tip (e.g. against an appendage attached at its tip or against an instrument held by the appendage against an undulating surface). For example, a 300 Series corrosion resistant stainless steel wire rope cable having a breaking strength rating of 920 pounds has been found to provide the strength needed for a flexible arm of about 9 inches in length.

The appendage can be in any shape adapted to the particular use to which the stabilizer arm assembly is to be put, such as a grabber, clipper, scissors, flat blade, and the like. In a preferred embodiment, as illustrated herein, the appendage 20 is a forked foot with two tines. In this embodiment, the two-tined stabilizer foot is shaped to be threaded through attachment sites located in a flexible suction body such as is described in copending U.S. Patent Application Serial No. 09/293,334, filed April 16, 1999, which is incorporated herein by reference in its entirety. In this embodiment, the stabilizer arm assembly is adapted to hold a suction body against the undulating surface of a beating heart during an "off pump coronary artery bypass" (OPCAB) procedure to

perform an anastomosis. Preferably, the invention stabilizer arm assembly is sized and adapted for use wherein the undulating surface is on the anterior side of the beating heart.

As shown in Figures 1-3, the mounting base 4 of the stabilizer arm assembly includes a clamp actuated by a rotatable clamp screw for removeably attaching the stabilizer arm assembly to a stationary fixture. As seen in cut-away in Figure 2, the clamping mechanism is actuated by turning rotatable clamping handle 10, which mates with the many-sided head 22 of the clamp screw 8 to advance moveable clamp foot 6 towards fixed clamp foot 7. Set screws 23 abut against opposite sides of head 22 and can be removed to remove clamping handle 10 for sterilization of the assembly, if desired. Set pin 24 is recessed within moveable clamp foot 6 and rides within a groove encircling the distal end of clamp screw 8 to force moveable foot 6 to advance towards fixed foot 7 as clamp screw 8 is rotated. In an alternative embodiment, the handles or interchangeable or a single handle can be used as the clamp tightening handle and the tightening handle. In this embodiment a nut used to attach the handle to the draw bar such that the nut move downs the draw bar as the tightening handle is rotated while the draw bar does not rotate. The bore in the handle is also dimensioned to attach to the head of the clamp screw. In this embodiment, the handle can readily be used to perform either function and then can be removed from the assembly for convenience during use.

The handles can be of any convenient size that does not interfere with use of the assembly. For example, if the invention assembly is to be used in surgery, it is convenient for the surgeon if the handles are about 3 inches in length and has a cross-sectional diameter at its largest dimension of about 2 inches to about 3 inches for ease in placing the flexible arm into a desired position at a treatment site, for example, for forceably holding a suction body in place on the surface of a beating heart. To avoid excessive weight, the handle can be partially hollow and can be fabricated of such materials as plastic or bakelite, and the like, by injection molding. Alternatively, the handle can be machined from metal or plastic, and the like, using techniques known in the art. In a preferred embodiment, tightening handle 12 is injection molded from Delrin 500 plastic and, for convenience during use is positioned at an angle of from about 0° to about 90° with respect to the face of the mounting base 4 at the point of attachment, for example at an angle of about 30° to about 45°. In this embodiment, the mounting clamp is preferably designed with dimensions compatible with most adult cardiac retractors. For example, the clamp is about 0.8 inch (2 cm) wide and accommodates rectangular sections ranging in thickness of 0.125 inch (0.32 cm) to 0.4 inch (1/02 cm) and widths of 0.25 inch to 1.5 inch (3.81 cm).

The flexible arm of invention stabilizer assemblies can be manipulated three-dimensionally, e.g., manually, to assume a desired shape and then are locked into whatever attitude is present when the tightening mechanism is actuated. However, once locked into a desired position, the arm becomes substantially rigid both along its length and at the point of greatest stress, i.e., the jointure of the arm to the mounting base. These attributes particularly suit the invention devices for holding an appendage attached to the turret joint (or an object attached to or held by the appendage) against any type of undulating surface. For example, a preferred use of the invention stabilizer assembly is for forceably holding a suction device motionless against a beating heart to stabilize the site for surgery. In other embodiments, the invention device can be used to hold an object against a grinding wheel during a grinding procedure, and the like.

For illustrative purposes the various parts of the flexible arm assembly have been fabricated from the following materials: Links 16 of the flexible arm are fabricated from 316 stainless steel, as are the appendage 20 and draw bar 40; joining piece 44 is fabricated from 17-4 stainless steel hardened; cable 30 is 300 series corrosion resistant stainless steel; set screws set pins and security screw are fabricated from 18-8 stainless steel and all other parts (except for the handles and the bearing housing in the thrust bearing) are fabricated from 18-8 stainless steel. However, various corrosion-resistant, hardened metallic materials, such as stainless steel, titanium, and the like, can be used when it is desired to machine the various parts of the invention flexible arm assembly. Alternatively, plastics or composites having comparable properties of strength and hardness can also be used to fabricate various parts of the assembly by methods known in the art, such as injection molding.

In the preferred embodiment, the flexible arm assembly is designed for repeated use (e.g., in medical applications) and hence is readily adapted to be sterilized for reuse. To facilitate sterilization, the tightening assembly can be loosened by rotating the tightening handle so as to partially backthread the cable out of the draw bar until the cable is visible between the links and connector 14 slides out of the mounting base. The security screw will prevent backthreading of the cable to the point that the apparatus comes apart. In this loosened state the assembly can readily be scrubbed to remove debris that may have lodged in the links. In addition, in embodiments wherein the assembly is manufactured of hardened metals, the complete assembly can be steam sterilizable. For example, in the preferred embodiment described herein, the assembly can be steam sterilized unwrapped at a temperature of about 132 °C, for 10 minutes in a gravity air displacement instrument. For a double wrapped instrument (double wrapped using a single use, non-woven, lint free fabric for sterile good wrapping), a suitable steam-cleaning temperature

is 121 °C for 30 minutes. When properly cared for as described herein, the invention flexible arm assembly can be reused (e.g, tightened, loosened and sterilized) a multitude of times, for example about 500 to 1000 times.

The invention flexible arm assembly can be lubricated to facilitate use, for example by complete immersion in a water-soluble lubricant for 30 seconds . Suitable lubrication agents are high viscosity lubricants that cling to the surface of metal when steam autoclaved, e.g. PRESERVE ™ Instrument Mild (Johnson & Johnson-Codman, Catalog No. 43-1033).

While the invention has been described in detail with reference to certain preferred embodiments thereof, it will be understood that modifications and variations are within the spirit and scope of that which is described and claimed.

CLAIMS

WHAT IS CLAIMED IS:

1. A stabilizer arm assembly for forceably holding an object against a surface, said assembly comprising:

a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture;

a flexible arm attached to the mounting base, said flexible arm comprising multiple articulated elongate links with each link being rotatably joined to adjacent links;

a turret joint comprising a freely rotatable socket attached to the distal-most link of the arm;

a holding appendage fixedly joined to the turret joint; and

a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint;

wherein actuation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-pressure is applied against the holding appendage.

2. The stabilizer arm according to claim 1 wherein the object is a surgical instrument and the surface is a beating heart.

3. The stabilizer arm according to claim 1 wherein the surface is a grinding surface.

4. A stabilizer arm assembly comprising:

a mounting base;

a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of uniform or graduated diminishing length from the proximal to the distal end thereof;

a jointing piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm;

a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket;

an appendage fixedly attached to the turret joint; and

a tightening mechanism loosely attaching together the mounting base, the joining piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint;

wherein actuation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm.

5. The stabilizer arm assembly according to claim 4 wherein the force is an undulating force.

6. The stabilizer arm assembly according to claim 4 wherein the force at the joining piece is from about one pound to about 150 pounds.

7. The stabilizer arm assembly according to claim 4 wherein the flexible arm is from about 2 inches to about 12 inches in length.

8. The stabilizer arm assembly according to claim 4 wherein each link is rotatably joined to adjacent links.

9. The stabilizer arm assembly according to claim 8 wherein the links have a substantially cylindrical segment with a knob attached at one end of the cylinder and a socket at the other end of the cylinder for receiving the knob of an adjacent link in the arm so as to rotatably join to the adjacent link.

10. The stabilizer arm assembly according to claim 9 wherein at least part of the surface of the knob is treated to increase the friction fit of the knob into the socket.

11. The stabilizer arm assembly according to claim 9 wherein the joining piece is a plate with a many-sided, centrally located opening therein for forceably receiving the knob of the proximal-most link.

12. The stabilizer arm assembly according to claim 11 wherein the joining piece is recessed into a slot in the mounting base to restrict movement of the knob of the proximal-most link within the socket in the mounting base upon actuation of the tightening mechanism.

13. The stabilizer arm assembly according to claim 12 wherein the joining piece is fabricated of harder metal than the knob of the proximal-most link.

14. The stabilizer arm assembly according to claim 13 wherein the joining piece replaceably slides into the slot.

15. The stabilizer arm assembly according to claim 4 wherein the tightening mechanism is connected between the distal end of the arm and the mounting base.

16. The stabilizer arm assembly according to claim 14 wherein the tightening mechanism comprises a rotatable tightening screw attached to a tightening cable, whereby rotation of the screw actuates the tightening mechanism to fix the attitude of the arm and turret joint.

17. The stabilizer arm assembly according to claim 16 wherein each of the plurality of links contains a hollow opening and the cable is threaded through the hollow openings to connect between the mounting base and the turret joint.

18. The stabilizer arm assembly according to claim 4 wherein deflection of the arm is curvilinear along the arm through an arc up to 360° and actuation of the tightening mechanism fixes the arm in such curvilinear attitude.

19. The stabilizer arm assembly according to claim 18 wherein deflection of the arm at the joining piece is from about 20° to 90° with respect to the face of the mounting base.

20. The stabilizer arm assembly according to claim 4 wherein deflection of the arm is three dimensional.

21. The stabilizer arm assembly according to claim 2 wherein the tightening mechanism further comprises a tightening screw assembly attached at the distal end to the cable and at the proximal end to a rotatable, replaceable handle for advancing the screw so as to shorten the effective length of the cable, thereby compressing together the links of the flexible arm.

22. The stabilizer arm assembly according to claim 20 wherein the tightening screw assembly can be sufficiently loosened for cleaning to completely expose each link in the flexible arm without allowing the flexible arm assembly to fall apart.

23. The stabilizer arm assembly according to claim 4 wherein the mounting base comprises a moveable clamp for removeably attaching the assembly to a stationary fixture.

24. The stabilizer arm assembly according to claim 4 wherein the appendage is a forked foot with tines for holding an object against a surface.

25. The stabilizer arm assembly according to claim 24 wherein the object is a cardiac suction body having apertures for receiving the tines of the forked foot.

26. The stabilizer arm assembly according to claim 4 wherein the appendage is a grabber, clipper, scissors, or flat blade.

27. The stabilizer arm assembly according to claim 4 wherein the appendage can freely spin through 360° at the jointure with the turret joint prior to actuation of the tightening mechanism.

28. The stabilizer arm assembly according to claim 4 wherein deflection of the appendage at the jointure with the turret joint is through a vertical angle of up to 120° prior to actuation of the tightening mechanism.

29. The stabilizer arm assembly according to claim 4 wherein the turret joint comprises a cylindrical member with a semi-circular slot-like cut-out in the side of the cylinder and the cable of the tightening mechanism has a ball at the distal end thereof that pivots or rotates within the semi-circular member and the cable translates along the slot prior to actuation of the tightening mechanism.

30. The stabilizer arm assembly according to claim 4 wherein the stabilizer arm assembly is constructed of stainless steel.

31. The stabilizer arm assembly according to claim 4 wherein the stabilizer arm assembly is steam sterilizable for reuse.

32. The stabilizer arm assembly according to claim 31 wherein the stabilizer arm assembly is steam sterilizable unwrapped at a temperature of about 132 °C, for 10 minutes.

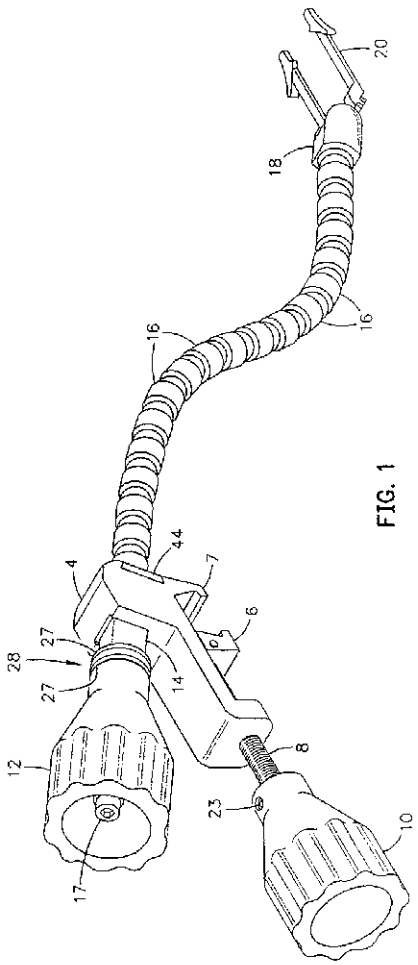
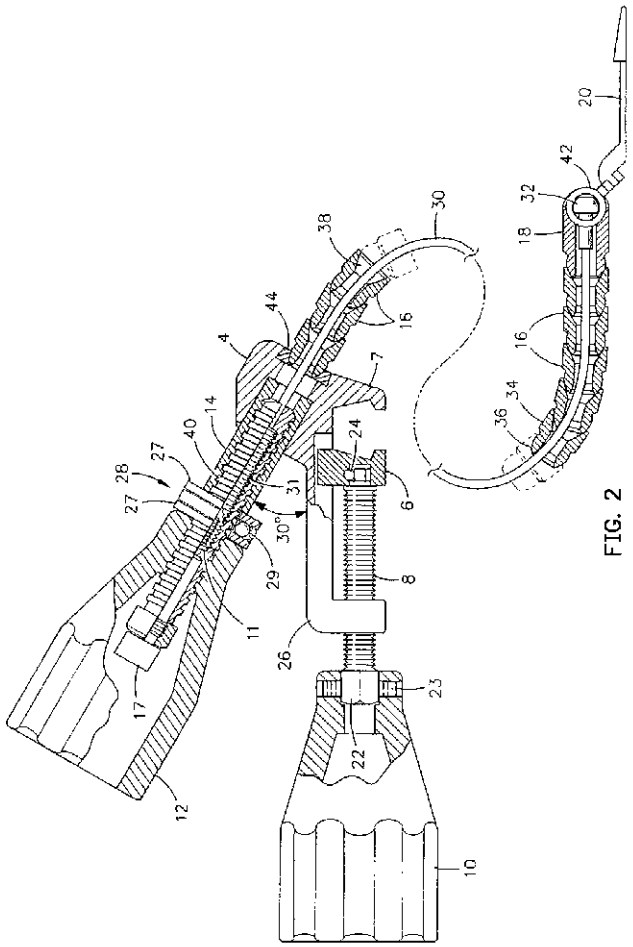


FIG. 1


20
42
32
18
16
34
36
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38
44
4
16
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31
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29
8
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26
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12
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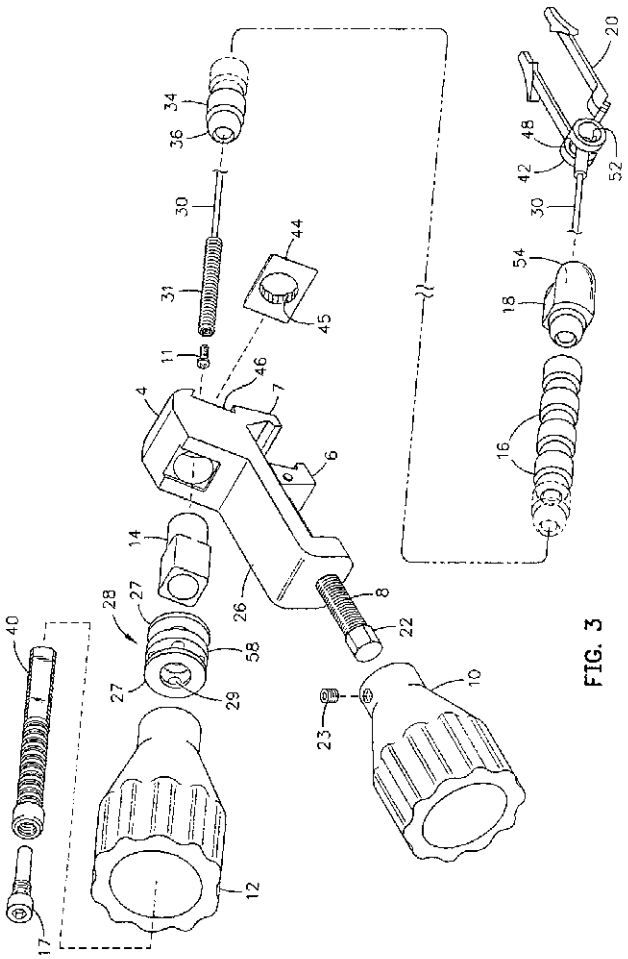
FIG. 2


20
48
42
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44
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29
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17

FIG. 3

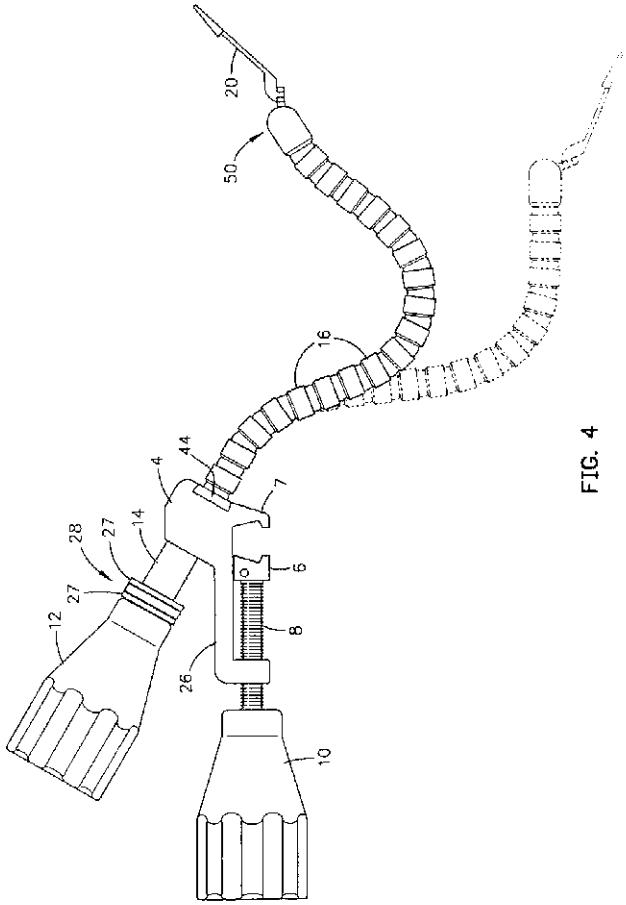

FIG. 4

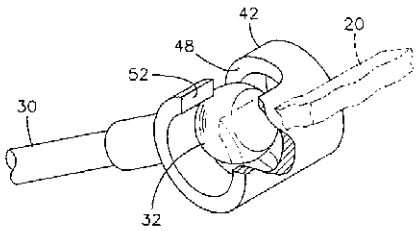

FIG. 5

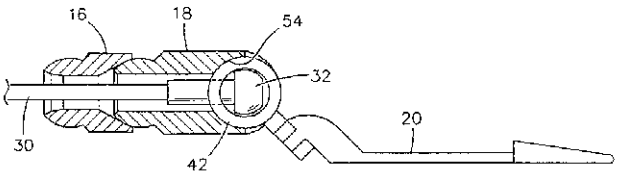

FIG. 6

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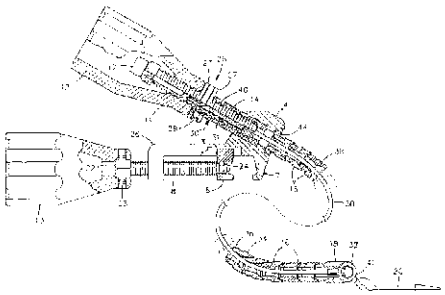
(54) Title: FLEXIBLE STABILIZER ARM FOR FORCIBLY HOLDING AN OBJECT AGAINST A SURFACE



(57) Abstract: The present invention provides a flexible stabilizer arm assembly (2) that can be positioned in a desired three-dimensioned attitude and then fixed in place to forceably holding an object against an undulating surface. In one embodiment, the invention assembly (2) comprises a mounting base (4) for attachment of the arm (3) to a stationary fixture, a flexible arm (3) of multiple articulated elongate links (16) rotatably joined to adjacent links (16), a freely rotatable turret joint (50) at the distal end of the arm (3) that is adapted to attach an appendage in freely rotatable fashion to the distal end of the arm (3).

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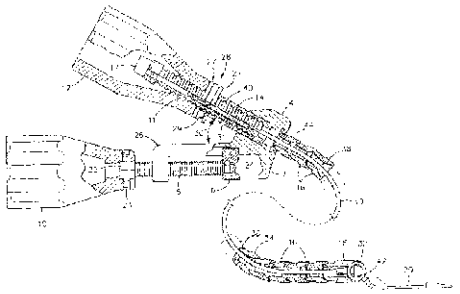

(57) Abstract: The present invention provides a flexible stabilizer arm assembly (2) that can be positioned in a desired three-dimensional attitude and then fixed in place to forceably holding an object against an undulating surface. In one embodiment, the invention assembly (2) comprises a mounting base (4) for attachment of the arm (3) to a stationary fixture, a flexible arm (3) of multiple articulated elongate links (16) rotatably joined to adjacent links (16), a free y rotatable turret joint (50) at the distal end of the arm (3) that is adapted to attach an appendage in freely rotatable fashion to the distal end of the arm (3).

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FLEXIBLE STABILIZER ARM FOR FORCIBLY HOLDING AN OBJECT AGAINST A SURFACE

FIELD OF THE INVENTION

The present invention generally relates to flexible holding members that lock into a desired shape. More particularly, the present invention relates to flexible articulated arms useful for forceably holding an object against a surface, particularly an undulating surface.

BACKGROUND OF THE INVENTION

Flexible arms that can be adjusted to a desired position or attitude and then "locked" into position serve a variety of uses in industry and in medicine. For example, such devices are useful for holding a light at a desirable angle or location, or for holding an object against a grinding wheel. However, in practice it is difficult to keep the flexible arm from moving after it has been "locked" into position if it is used to hold or support a heavy object or when used to forceably hold an object against a surface, particularly against an undulating surface.

When adapted for attachment to a stationary object, such as a chest retractor, a flexible arm can be used during surgery for holding a medical device in a desired location. It has proven particularly difficult to obtain a flexible arm that can be used in this fashion to position and hold a device, such as a suction body, against the undulating surface of a beating heart while applying sufficient pressure to the surface of the heart to stabilize an area on the surface of the heart for surgery. The constant movement of the undulating surface tends to break down the "set" of the arm, leading to eventual loss of rigidity and even collapse.

If the surgical site is on the anterior side of the heart (when the patient is lying on his back), it would be desirable to have a stabilizer arm long enough to attach and stabilize the suction device against the anterior side of the heart. However, in an articulated flexible arm of multiple links, the longer the arm, the harder it is to keep the arm rigid once it is in place and locked into position. Each jointure between two links in

the articulated arm is a potential site of movement, and the greatest moment of movement is at the jointure of the flexible arm to the base used to mount the arm upon a stationary object. This difficulty is compounded when the surface against which the arm is to be placed is in constant movement, such as the surface of a beating heart.

Accordingly, there is still a need in the art for flexible holding members that lock into a desired shape. More particularly, there is still a need in the art for flexible articulated arms useful for forceably holding an object against a surface, particularly an undulating surface.

BRIEF DESCRIPTION OF THE INVENTION

The present invention overcomes many of the problems in the art by providing stabilizer arm assemblies for forceably holding an object against a surface. The invention stabilizer arm assembly comprises a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture; a flexible arm attached to the mounting base, said flexible arm comprising multiple articulated elongate links with each link being rotatably joined to adjacent links; a turret joint comprising a freely rotatable socket attached to the distal-most link of the arm; a holding appendage fixedly joined to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly compressed together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage.

In another embodiment, the invention provides a stabilizer arm assembly comprising a mounting base; a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of graduated diminishing length from the proximal to the distal end thereof; a joining piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm; a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket; an appendage fixedly

attached to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the joining piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint. Acutation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is a perspective drawing showing the invention stabilizer arm assembly locked into a fixed attitude.

Figure 2 is a cut-away drawing showing the tightening mechanism running down the central axis of the flexible arm. At the distal end of the cable assembly, a ball attached to the distal end of the cable is held within the turret joint, to which an appendage (foot) is fixedly attached. A cut-away of the clamping handle shows the mechanism of the clamping screw, which is used to removeably attach the flexible arm assembly to a stationary fixture.

Figure 3 is an exploded drawing showing a preferred embodiment of the invention flexible arm assembly.

Figure 4 is a schematic drawing showing the invention flexible arm locked into a fixed attitude by actuation of the tightening mechanism. The position of the flexible arm prior to positioning and actuation of the tightening mechanism is shown in phantom (dotted lines).

Figure 5 is an isometric drawing showing in partial cut-away the cable ball captured within the cylindrical connector in the turret joint. The appendage, which is is attached to the exterior of the connector is shown in phantom.

Figure 6 is a cut-away drawing down the median of the distal end of the invention flexible arm assembly showing the cable ball riding within the turret joint and the appendage attached to the exterior of the turret joint.

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the present invention, there are provided stabilizer arm assemblies for forceably holding an object against an undulating surface. In one embodiment, the invention stabilizer arm assembly comprises a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture; a flexible arm attached to the mounting base; a turret joint comprising a freely rotatable socket attached to the distal-most link of the arm; a holding appendage fixedly joined to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint. The flexible arm comprises multiple articulated elongate links with each link being rotatably joined to adjacent links. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly compresses together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the holding appendage.

In another embodiment, the invention provides a stabilizer arm assembly comprising a mounting base; a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of uniform or graduated diminishing length from the proximal to the distal end thereof; a joining piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm; a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket; an appendage fixedly attached to the turret joint; and a tightening mechanism loosely attaching together the mounting base, the joining piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint. The flexible arm comprises multiple articulated elongate links with each link being rotatably joined to adjacent links. Acutation of the tightening mechanism rigidly compresses together the turret joint, the

links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm. For example, the force at the joining piece can be from about one pound to about 150 pounds.

In one embodiment, the tightening mechanism is actuated by advancing a tightening screw attached to the cable to increase tension in the cable, thereby forcing the links of the arm together, restricting motion of the links relative to one another. Thus, tightening of the tightening mechanism locks the multiple links into the desired position. To exert sufficient tension on the links to provide rigidity to the arm without breaking, the cable preferably has a breaking strength (to withstand high tensile force) in the range from about 500 to 1000 pounds force, such as 300 series corrosion resistant stainless steel.

The preferred embodiments of the invention flexible arm assembly are described with reference to Figures 1-5. As shown in Figure 1, flexible arm assembly 2 comprises a flexible arm 3 having a plurality of links 16, ending at the distal tip in turret joint 50, which is comprised of spherical coupling 18 and appendage connector 42 (shown in detail in Figures 5 and 6), to which is attached appendage 20. The combination of spherical coupling 18 and appendage connector 42 forms turret joint 50. The flexible arm 3 is attached at the proximal end to mounting base 4. Tightening handle 12 is also attached to mounting base 4 via control screw 17, thrust bearing 22, and slideable connector 14, which is received into an internal bore within mounting base 4. Mounting base 4 further comprises a mounting mechanism comprising fixed clamp foot 7, moveable clamp foot 6, and actuating clamp screw 8. Rotatable clamp screw handle 10 is rotated to advance moveable clamp foot 6 towards fixed clamp foot 7 to clamp the mounting assembly to a stationary fixture.

The flexibility of the flexible arm in the invention flexible arm assembly is increased by having segments of shorter length, but the shorter the segments, the less strength (e.g., the arm is more difficult to lock into a rigid position or will become unstable when a force is applied to the distal tip). The relative length and other

dimensions of the links can be determined by the materials used to fabricate the arm (e.g., the weight of the materials), and the intended purpose. For example, it has been determined that, for an arm in an invention device intended for use in beating heart surgery (which requires a high degree of flexibility to position the arm accurately) the optimum combination of flexibility and strength is achieved by having multiple links of uniform size, for example about 0.5 inch in length or less for a total arm length of about 2 inches to 12 inches when fabricated of 316 grade stainless steel. This configuration results in uniform distribution of stress along the flexible arm, thus preventing excessive wear on any particular link. However, in another embodiment the links in the arm can have diminishing graduated length from the proximal to the distal end thereof. For example, a flexible arm comprised of the following set of links of graduated diminishing length from the proximal to the distal end of the arm has also proven useful: two links of one inch (located most proximally), two links of ¾ inch, and four links of ½ inch (located most distally), for a total of 5 ½ inches. At a length greater than about 12 inches (30 cm), even if the arm if fabricated of stainless steel, it has been found impossible to maintain the arm in a fixed position when a force as great as 12 pounds is applied against the distal tip (i.e., the appendage).

Preferably, to enhance flexibility of the arm, each link is rotatably joined to adjacent links. For example, as shown in cut-away in Figure 2, links 16 of the flexible arm comprise a substantially cylindrical segment 34, with knob 36 at one end of the cylindrical segment of the link and concave socket 38 recessed into the opposite end of the cylindrical segment of the link. The knob at one end of the cylindrical link is received into the socket recessed at the end of an adjacent link so as to rotatably join to the adjacent link when the flexible arm remains loosened. However, when it is desired to fix the attitude of the arm prior to use by tightening the tightening mechanism, each jointure of two adjacent links is a potential site of movement. To aid in stabilizing the arm upon actuation of the tightening mechanism, at least a portion of the surface of the knobs 36 can be treated to increase the friction fit of the knobs into the sockets. For example, the surfaces of the knobs at the end of the links can be coated with a friction-inducing substance. However, it is possible that a surface coating will erode during use, forming flakes of coating. If the stabilizer assembly is to be used at a surgical site, the

flakes of coating may be undesirable. Consequently, in this situation, it is preferred to roughen at least part of the surface of the knobs in the flexible arm to increase the friction fit of the knob 36 into the socket of the adjoining link. For example, metal knobs can be scored with a fine pattern by turning the knobs at low speed to cut a groove pattern in the knobs.

Preferably, the knobs of the links of the flexible arm have a generally convex (e.g., substantially spherical) portion that attaches to the cylindrical portion of the link, but are more flattened at the head of the knob (the portion most distant from the cylindrical portion of the link). The sockets in the cylindrical portion of the links can have a corresponding concave shape (e.g., semi-spherical) to receive the convex knobs. Due to the knob and socket jointures between the links of the arm, the flexible arm is freely deformable in three dimensions and/or can assume an "O" or "S" shape, if desired, as shown in Figure 2. In other words, the flexible arm can have up to 360° of curvature along its length and can flex in a sideways motion as well as in a vertical plane.

The segments (i.e., links 16) of the flexible arm can be manufactured of any substance having sufficient hardness and strength for the intended purpose. The jointure of the flexible arm to the rigid mounting base is the point that experiences the greatest force when the arm is locked into a fixed position and a counter-force is applied against the distal tip of the arm, e.g., via an appendage fixed at the distal tip. To further provide strength and rigidity when the arm is locked into position, the invention flexible arm assembly further comprises a joining piece 44 located at the jointure of the flexible arm 3 to the rigid mounting base 4. The joining piece 44 is designed to enhance friction in the jointure between the mounting base 4 and the proximal-most link 16. Preferably, the joining piece is made of hardened metal (i.e. a metal harder than that used to fabricate the proximal most link) and is positioned to be replaceable. For example, if the articulated arm is comprised of multiple links joined together in a knob and socket assembly, as described above, the joining piece 44 can consist of a plate or disc having a many-sided opening 45 into which the knob of the proximal-most link is forceably compressed upon actuation of the tightening mechanism. Preferably the opening 45 in the joining piece is a double hex arranged to provide points and valleys around the opening so that the points will dig into the proximal-most link of the flexible arm when

tightened. In this embodiment, the jointure of the proximal-most link to the mounting base can withstand a force of from about one pound to about 150 pounds while the joining piece substantially eliminates movement of the arm with respect to the mounting base. In alternative embodiments the opening can have from about 6 to about 30 sides. The many-sided opening 45 provides a greater resistance to movement of the knob within the opening than would a smooth and curvilinear opening.

As shown in Figure 3, the joining piece 44 is a plate that slides into a slot 46, which as beveled edges to replaceably hold the joining piece into the slot cut in mounting base 4. Because the joining piece is many-sided rather than curvilinear, the knob in the socket within the mounting base will be more restricted in movement by the joining piece than are the knobs in the curvilinear sockets in the balance of the flexible arm, thus providing enhanced rigidity to the invention assembly at the point of greatest force during use of the assembly to hold an object against a surface, such as an undulating surface.

As also shown in Figure 3, connector 42 is permanently attached to the proximal end of appendage 20 (shown here as a forked foot). For example, connector 42 can be welded to appendage 20. As further shown in detail in Figures 5 and 6, the turret joint 50 is formed by spherical coupling 18 at the distal tip of the flexible arm 3 and appendage connector 42 so a to attach appendage 20 to flexible arm 3 in a freely rotatable manner (i.e., to flex in a vertical plane as well as to freely rotate or spin at the end of the flexible arm) until the tightening mechanism is actuated. Spherical coupling 18 comprises a knob that fits into the concave recess of its adjoining link in the arm, a cylindrical middle portion, and a distal portion with semi-spherical socket 54 for receiving the cylindrical-shaped portion 56 of appendage connector 42. Connector 42 comprises a cylindrical-shaped portion with internal bore sized to receive the ball of the cable and which has a slot-like cut-out 48 running semi-circumferentially around the side of the cylinder, providing an opening that connects with the internal bore. An additional cut out 52 is at right angles to the slot-like cut-out 48 and is sized to allow the cable to slide through cut out 52 while ball 32 is received into the bore of cylindrical connector 42.

Ball 32 at the distal end of cable 30 (shown in Figure 2) is preferably a ball and shank fitting which is swaged onto the end of cable 30. Ball 32 is held within pivot joint 50 by the sides of the semi-spherical socket 54 in spherical coupling 18 and pivots or rotates 360° within the bore of the cylindrical connector 42 while the cable translates along slot-like cut-out 48, giving a deflection of the appendage (like a foot at an ankle joint), for example a deflection of up to about 120° as shown here. Thus the appendage is freely rotatable within the pivot joint and has a large range of flexure to facilitate accurate positioning of the appendage against any contour of a surface until the arm and turret joint is locked into a fixed attitude by actuation of the tightening mechanism. Ball 32 can be modified by placing a flat on the surface closes to the shank to move and spread the force away from the slot in connector 42.

The tightening mechanism connects together the distal portion of the arm and the proximal end of the stabilizer assembly (e.g., the mounting base) and locks the links of the flexible arm into a fixed attitude. Before tightening, the connection between the various parts of the assembly are loosely joined by the cable, which connects together mounting base 4, the plurality of links 16 of the flexible arm, and the freely rotatable socket of the turret joint 50 via cable 30 and ball 32. Upon actuation of the tightening mechanism, the turret joint, the links of the arm and the mounting base are rigidly compressed together so as to hold the assembly in a fixed attitude while from about one to about twenty pounds, for example from about five to about twelve pounds, of counter-force is applied against the holding appendage.

More particularly, as shown in exploded view in Figure 3, the tightening mechanism comprises (from proximal to distal end) control screw 17, draw bar 40, cable 30 with internal, security screw 11 (that screws into internal threads along the proximal-most end of exteriorly threaded and swaged portion 31 of cable 30) and cable ball 32, which is fixedly attached at the distal end of cable 30. The proximal portion of draw bar 40 is generally cylindrical with an interior bore and external threads that mate with internal threads along an internal bore within handle 12. However, the distal portion of draw bar 40 has flatted sides and the interior bore is lined with internal threads that mate with the external threads on the threaded and swaged portion 31 of cable 30. Preferably, the external threads on the draw bar and

the mating internal threads on handle 12 are acme threads for added strength while the internal threads along the bore of draw bar 40 and the mating external, swaged threads along the threaded portion 31 of cable 30 are pointed.

When the assembly is assembled as shown in Figure 1, slideable connector 14 is used to join together draw bar 40, handle 12 and the flexible arm threaded through with the cable assembly and attached appendage. Slideable connector 14 has a distal end with a cylindrical exterior portion and an interior bore with flatted sides designed to receive the distal end (with mating flatted sides) of draw bar 40. The cylindrical exterior portion of connector 14 is sized to slide into a bore hole through mounting base 4. Slideable connector 14 also comprises a proximal portion with a smooth interior bore and squared exterior sized to sit flush against the exterior of distal washer 17. The proximal, threaded portion of cable 30 is passed through an interior smooth bore in connector 14 through washers 27 and thrust bearing 28 and the bore of handle 12. Draw bar 40 passes through the large opening the in proximal end of handle 12 and is threaded via the exterior threads thereon into the mating interior threads in the bore of handle 12. The thrust bearing 28 is a three piece assembly of two washers 27 and a set of steel bearings 29, which are encased in a slightly compressible material , such as nylon. Thrust bearing 28 facilitates rotation of the tightening handle 12 as the various parts of the assembly are compressed together by effective shortening of the cable (i.e., by advancement of the threaded portion 31 of cable 30 proximally within the draw bar). Thrust bearing 28 compresses somewhat as the tightening mechanism is tightened to prevent sudden application of greater tensile force than can be tolerated by the assembly.

When handle 12 is rotated, the threaded portion of the cable advances proximally up the handle, while the handle advances distally along the draw bar. Security screw 11, which screws into the interior threads at the proximal end of the threaded portion of the cable, also fits into a recess in the proximal end of draw bar 40 and is sized with respect to the interior bore of the draw bar to lodge against shoulders therein created by a small decrease in the internal diameter of the interior bore in the draw bar. Thus, security screw 11, which is inserted into the end of the cable assembly using a long handled Allen wrench applied through the proximal opening of

handle 12, functions to prevent backthreading of the cable completely out of the draw bar. Control screw 17, which is inserted last, has a hex head for receiving an Allen wrench and screws into the interior threads at the proximal end of the draw bar. Control screw 17 functions to keep alignment of the assembly and to prevent threading of the cable too far into the draw bar.

Cable 30 can be manufactured of any substance having sufficient tensile strength to provide the invention flexible arm assembly with the capability to remain rigid when up to about twenty pounds of counter-force is applied against its tip (e.g. against an appendage attached at its tip or against an instrument held by the appendage against an undulating surface). For example, a 300 Series corrosion resistant stainless steel wire rope cable having a breaking strength rating of 920 pounds has been found to provide the strength needed for a flexible arm of about 9 inches in length.

The appendage can be in any shape adapted to the particular use to which the stabilizer arm assembly is to be put, such as a grabber, clipper, scissors, flat blade, and the like. In a preferred embodiment, as illustrated herein, the appendage 20 is a forked foot with two tines. In this embodiment, the two-tined stabilizer foot is shaped to be threaded through attachment sites located in a flexible suction body such as is described in copending U.S. Patent Application Serial No. 09/293,334, filed April 16, 1999, which is incorporated herein by reference in its entirety. In this embodiment, the stabilizer arm assembly is adapted to hold a suction body against the undulating surface of a beating heart during an "off pump coronary artery bypass" (OPCAB) procedure to perform an anastomosis. Preferably, the invention stabilizer arm assembly is sized and adapted for use wherein the undulating surface is on the anterior side of the beating heart.

As shown in Figures 1-3, the mounting base 4 of the stabilizer arm assembly includes a clamp actuated by a rotatable clamp screw for removeably attaching the stabilizer arm assembly to a stationary fixture. As seen in cut-away in Figure 2, the clamping mechanism is actuated by turning rotatable clamping handle 10, which mates with the many-sided head 22 of the clamp screw 8 to advance moveable clamp foot 6

towards fixed clamp foot 7. Set screws 23 abut against opposite sides of head 22 and can be removed to remove clamping handle 10 for sterilization of the assembly, if desired. Set pin 24 is recessed within moveable clamp foot 6 and rides within a groove encircling the distal end of clamp screw 8 to force moveable foot 6 to advance towards fixed foot 7 as clamp screw 8 is rotated. In an alternative embodiment, the handles or interchangeable or a single handle can be used as the clamp tightening handle and the tightening handle. In this embodiment a nut used to attach the handle to the draw bar such that the nut move downs the draw bar as the tightening handle is rotated while the draw bar does not rotate. The bore in the handle is also dimensioned to attach to the head of the clamp screw. In this embodiment, the handle can readily be used to perform either function and then can be removed from the assembly for convenience during use.

The handles can be of any convenient size that does not interfere with use of the assembly. For example, if the invention assembly is to be used in surgery, it is convenient for the surgeon if the handles are about 3 inches in length and has a cross-sectional diameter at its largest dimension of about 2 inches to about 3 inches for ease in placing the flexible arm into a desired position at a treatment site, for example, for forceably holding a suction body in place on the surface of a beating heart. To avoid excessive weight, the handle can be partially hollow and can be fabricated of such materials as plastic or bakelite, and the like, by injection molding. Alternatively, the handle can be machined from metal or plastic, and the like, using techniques known in the art. In a preferred embodiment, tightening handle 12 is injection molded from Delrin 500 plastic and, for convenience during use is positioned at an angle of from about 0° to about 90° with respect to the face of the mounting base 4 at the point of attachment, for example at an angle of about 30° to about 45°. In this embodiment, the mounting clamp is preferably designed with dimensions compatible with most adult cardiac retractors. For example, the clamp is about 0.8 inch (2 cm) wide and accommodates rectangular sections ranging in thickness of 0.125 inch (0.32 cm) to 0.4 inch (1/02 cm) and widths of 0.25 inch to 1.5 inch (3.81 cm).

The flexible arm of invention stabilizer assemblies can be manipulated three-dimensionally, e.g., manually, to assume a desired shape and then are locked into

whatever attitude is present when the tightening mechanism is actuated. However, once locked into a desired position, the arm becomes substantially rigid both along its length and at the point of greatest stress, i.e., the jointure of the arm to the mounting base. These attributes particularly suit the invention devices for holding an appendage attached to the turret joint (or an object attached to or held by the appendage) against any type of undulating surface. For example, a preferred use of the invention stabilizer assembly is for forceably holding a suction device motionless against a beating heart to stabilize the site for surgery. In other embodiments, the invention device can be used to hold an object against a grinding wheel during a grinding procedure, and the like.

For illustrative purposes the various parts of the flexible arm assembly have been fabricated from the following materials: Links 16 of the flexible arm are fabricated from 316 stainless steel, as are the appendage 20 and draw bar 40; joining piece 44 is fabricated from 17-4 stainless steel hardened; cable 30 is 300 series corrosion resistant stainless steel; set screws set pins and security screw are fabricated from 18-8 stainless steel and all other parts (except for the handles and the bearing housing in the thrust bearing) are fabricated from 18-8 stainless steel. However, various corrosion-resistant, hardened metallic materials, such as stainless steel, titanium, and the like, can be used when it is desired to machine the various parts of the invention flexible arm assembly. Alternatively, plastics or composites having comparable properties of strength and hardness can also be used to fabricate various parts of the assembly by methods known in the art, such as injection molding.

In the preferred embodiment, the flexible arm assembly is designed for repeated use (e.g., in medical applications) and hence is readily adapted to be sterilized for reuse. To facilitate sterilization, the tightening assembly can be loosened by rotating the tightening handle so as to partially backthread the cable out of the draw bar until the cable is visible between the links and connector 14 slides out of the mounting base. The security screw will prevent backthreading of the cable to the point that the apparatus comes apart. In this loosened state the assembly can readily be scrubbed to remove debris that may have lodged in the links. In addition, in embodiments wherein the assembly is manufactured of hardened metals, the complete assembly can be steam sterilizable. For example, in the preferred embodiment described herein, the

assembly can be steam sterilized unwrapped at a temperature of about 132 °C, for 10 minutes in a gravity air displacement instrument. For a double wrapped instrument (double wrapped using a single use, non-woven, lint free fabric for sterile good wrapping), a suitable steam-cleaning temperature is 121 °C for 30 minutes. When properly cared for as described herein, the invention flexible arm assembly can be reused (e.g, tightened, loosened and sterilized) a multitude of times, for example about 500 to 1000 times.

The invention flexible arm assembly can be lubricated to facilitate use, for example by complete immersion in a water-soluble lubricant for 30 seconds . Suitable lubrication agents are high viscosity lubricants that cling to the surface of metal when steam autoclaved, e.g. PRESERVE ™ Instrument Mild (Johnson & Johnson-Codman, Catalog No. 43-1033).

While the invention has been described in detail with reference to certain preferred embodiments thereof, it will be understood that modifications and variations are within the spirit and scope of that which is described and claimed.

WHAT IS CLAIMED IS:

1. A stabilizer arm assembly for forceably holding an object against a surface, said assembly comprising:

a mounting assembly comprising a mounting base and moveable mounting clamp for removeably clamping the stabilizer arm assembly to a stationary fixture;

a flexible arm attached to the mounting base, said flexible arm comprising multiple articulated elongate links with each link being rotatably joined to adjacent links;

a turret joint comprising a freely rotatable socket attached to the distal-most link of the arm;

a holding appendage fixedly joined to the turret joint; and

a tightening mechanism loosely attaching together the mounting base, the multiple links of the arm, and the freely rotatable socket of the turret joint;

wherein actuation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-pressure is applied against the holding appendage.

2. The stabilizer arm according to claim 1 wherein the object is a surgical instrument and the surface is a beating heart.

3. The stabilizer arm according to claim 1 wherein the surface is a grinding surface.

4. A stabilizer arm assembly comprising:

a mounting base;

a flexible arm attached at the proximal end thereof to the mounting base, said flexible arm comprising a plurality of articulated links of uniform or graduated diminishing length from the proximal to the distal end thereof;

a joining piece that enhances the friction in the jointure between the mounting base and the proximal-most link of the flexible arm;

a turret joint comprising a freely rotatable socket, being attached to the distal-most link of the arm via the freely rotatable socket;

an appendage fixedly attached to the turret joint; and

a tightening mechanism loosely attaching together the mounting base, the joining piece, the plurality of links of the flexible arm, and the freely rotatable socket of the turret joint;

wherein actuation of the tightening mechanism rigidly compresses together the turret joint, the links of the arm, the joining piece, and the mounting base so as to hold the assembly in a fixed attitude while from about one to about twenty pounds of counter-force is applied against the appendage and wherein the joining piece resists a greater force than the force at jointures between adjacent links of the arm.

5. The stabilizer arm assembly according to claim 4 wherein the force is an undulating force.

6. The stabilizer arm assembly according to claim 4 wherein the force at the joining piece is from about one pound to about 150 pounds.

7. The stabilizer arm assembly according to claim 4 wherein the flexible arm is from about 2 inches to about 12 inches in length.

8. The stabilizer arm assembly according to claim 4 wherein each link is rotatably joined to adjacent links.

9. The stabilizer arm assembly according to claim 8 wherein the links have a substantially cylindrical segment with a knob attached at one end of the cylinder and a socket at the other end of the cylinder for receiving the knob of an adjacent link in the arm so as to rotatably join to the adjacent link.

10. The stabilizer arm assembly according to claim 9 wherein at least part of the surface of the knob is treated to increase the friction fit of the knob into the socket.

11. The stabilizer arm assembly according to claim 9 wherein the joining piece is a plate with a many-sided, centrally located opening therein for forceably receiving the knob of the proximal-most link.

12. The stabilizer arm assembly according to claim 11 wherein the joining piece is recessed into a slot in the mounting base to restrict movement of the knob of the proximal-most link within the socket in the mounting base upon actuation of the tightening mechanism.

13. The stabilizer arm assembly according to claim 12 wherein the joining piece is fabricated of harder metal than the knob of the proximal-most link.

14. The stabilizer arm assembly according to claim 13 wherein the joining piece replaceably slides into the slot.

15. The stabilizer arm assembly according to claim 4 wherein the tightening mechanism is connected between the distal end of the arm and the mounting base.

16. The stabilizer arm assembly according to claim 14 wherein the tightening mechanism comprises a rotatable tightening screw attached to a tightening cable, whereby rotation of the screw actuates the tightening mechanism to fix the attitude of the arm and turret joint.

17. The stabilizer arm assembly according to claim 16 wherein each of the plurality of links contains a hollow opening and the cable is threaded through the hollow openings to connect between the mounting base and the turret joint.

18. The stabilizer arm assembly according to claim 4 wherein deflection of the arm is curvilinear along the arm through an arc up to 360° and actuation of the tightening mechanism fixes the arm in such curvilinear attitude.

19. The stabilizer arm assembly according to claim 18 wherein deflection of the arm at the joining piece is from about 20° to 90° with respect to the face of the mounting base.

20. The stabilizer arm assembly according to claim 4 wherein deflection of the arm is three dimensional.

21. The stabilizer arm assembly according to claim 2 wherein the tightening mechanism further comprises a tightening screw assembly attached at the distal end to the cable and at the proximal end to a rotatable, replaceable handle for advancing the screw so as to shorten the effective length of the cable, thereby compressing together the links of the flexible arm.

22. The stabilizer arm assembly according to claim 20 wherein the tightening screw assembly can be sufficiently loosened for cleaning to completely expose each link in the flexible arm without allowing the flexible arm assembly to fall apart.

23. The stabilizer arm assembly according to claim 4 wherein the mounting base comprises a moveable clamp for removeably attaching the assembly to a stationary fixture.

24. The stabilizer arm assembly according to claim 4 wherein the appendage is a forked foot with tines for holding an object against a surface.

25. The stabilizer arm assembly according to claim 24 wherein the object is a cardiac suction body having apertures for receiving the tines of the forked foot.

26. The stabilizer arm assembly according to claim 4 wherein the appendage is a grabber, clipper, scissors, or flat blade.

27. The stabilizer arm assembly according to claim 4 wherein the appendage can freely spin through 360° at the jointure with the turret joint prior to actuation of the tightening mechanism.

28. The stabilizer arm assembly according to claim 4 wherein deflection of the appendage at the jointure with the turret joint is through a vertical angle of up to 120° prior to actuation of the tightening mechanism.

29. The stabilizer arm assembly according to claim 4 wherein the turret joint comprises a cylindrical member with a semi-circular slot-like cut-out in the side of the cylinder and the cable of the tightening mechanism has a ball at the distal end thereof that pivots or rotates within the semi-circular member and the cable translates along the slot prior to actuation of the tightening mechanism.

30. The stabilizer arm assembly according to claim 4 wherein the stabilizer arm assembly is constructed of stainless steel.

31. The stabilizer arm assembly according to claim 4 wherein the stabilizer arm assembly is steam sterilizable for reuse.

32. The stabilizer arm assembly according to claim 31 wherein the stabilizer arm assembly is steam sterilizable unwrapped at a temperature of about 132 °C. for 10 minutes.

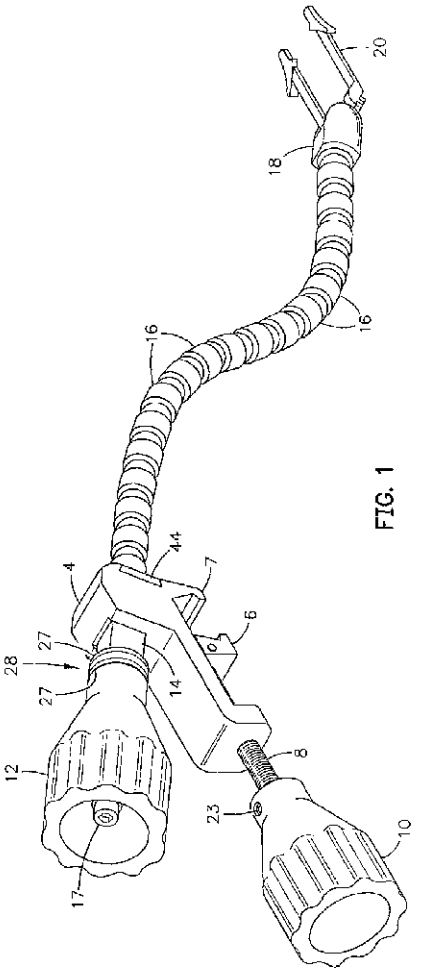

FIG. 1

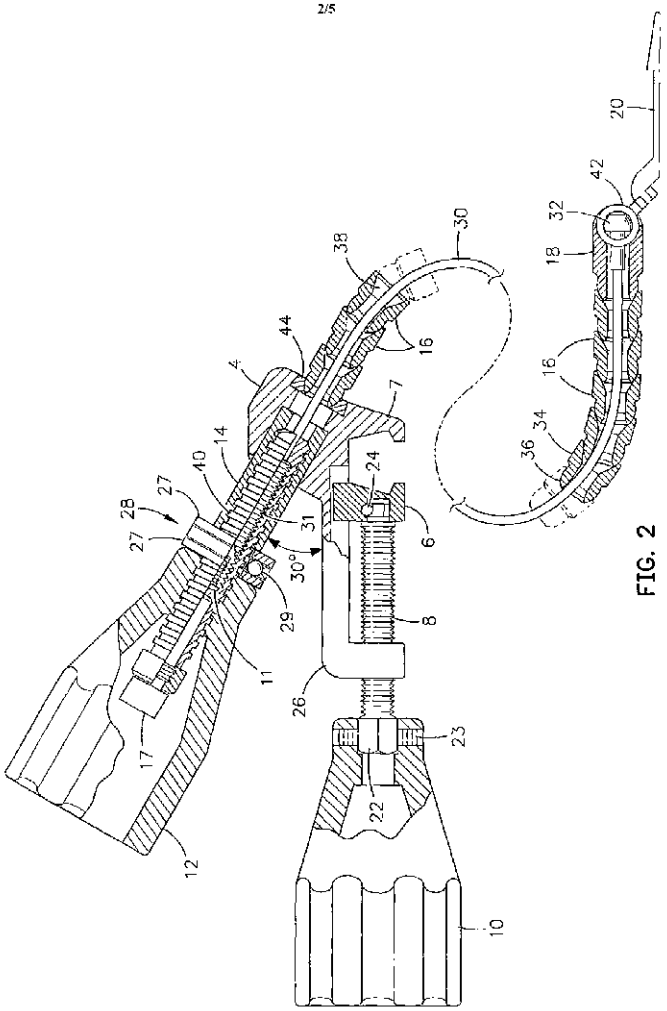
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FIG. 2

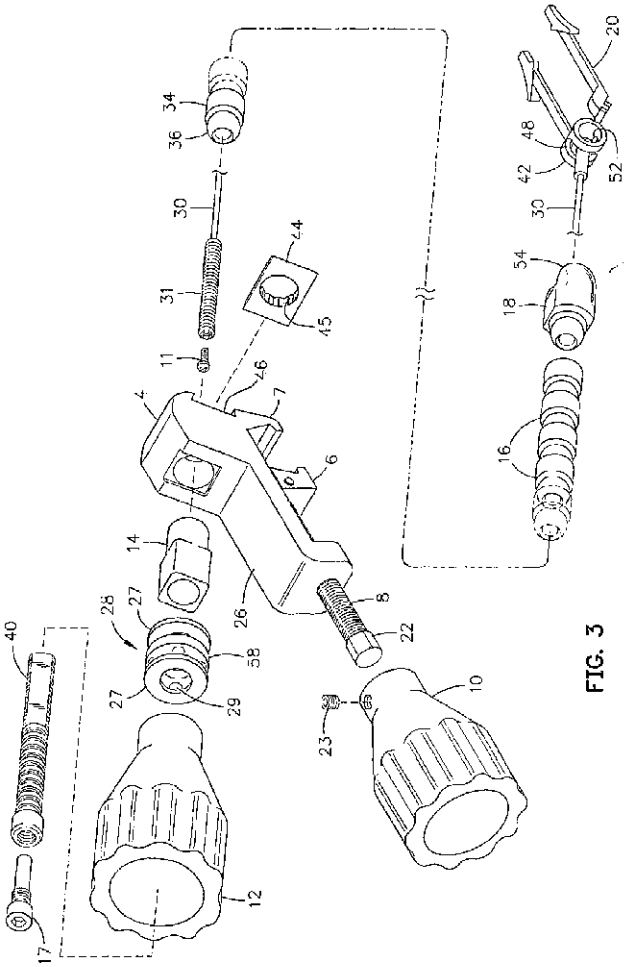
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FIG. 3

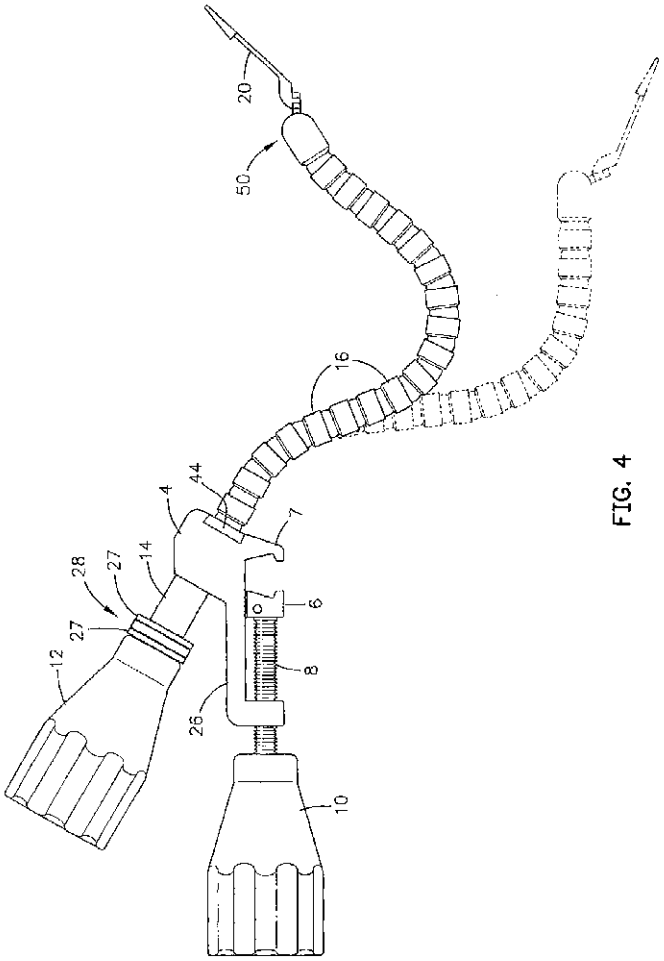

FIG. 4

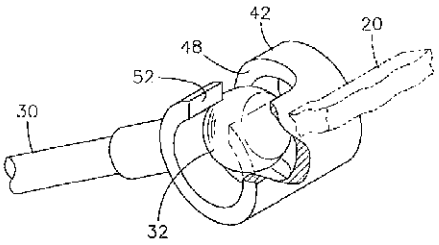

FIG. 5

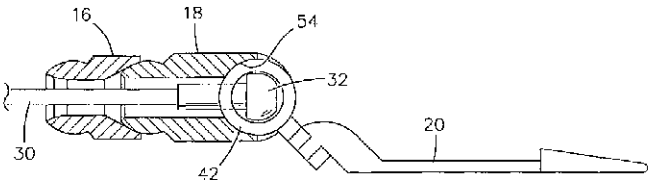

FIG. 6

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/00865

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61F 2/00, 13/00
US CL : 600/37
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 600/37, 301, 305, 211, 235, 213, 215, 236-239; 128/898, 897; 249/876.1, 898.51, 316.4

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WEST: heart, stabilize, link, arm, socket, flexible, base, joint, actuator

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,899,425 A (COREY, JR. et al) 04 May 1999, see whole document.	1-32
Y	US 6,007,486 A (HUNT et al) 28 December 1999, see whole document.	1-32
Y,E	US 6,213,941 B1 (BENETTI et al) 10 April 2001, see whole document.	1-32
Y	US 5,947,896 A (SHERTS et al) 07 September 1999, see whole document.	1-32
Y,P	US 6,036,641 A (TAYLOR et al) 14 March 2000, see whole document.	1-32

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 JUNE 2001	30 AUG 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer BRIAN SZMAL Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)*

フロントページの続き

(81)指定国 AP(GH,GM,KE,LS,MW,MZ,SD,SL,SZ,TZ,UG,ZW),EA(AM,AZ,BY,KG,KZ,MD,RU,TJ,TM),EP(AT,BE,CH,CY,DE,DK,ES,FI,FR,GB,GR,IE,IT,LU,MC,NL,PT,SE,TR),OA(BF,BJ,CF,CG,CI,CM,GA,GN,GW,ML,MR,NE,SN,TD,TG),AG,AL,AM,AT,AU,AZ,BA,BB,BG,BR,BY,BZ,CA,CH,CN,CU,CZ,DE,DK,DZ,EE,ES,FI,GB,GD,GE,GH,GM,HR,HU,ID,IL,IN,IS,JP,KE,KG,KP,KR,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,MZ,NO,NZ,PL,PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,US,UZ,VN,YU,ZW

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【要約の続き】
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【選択図】図２