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— *with international search report (Art. 21(3))*

[Continued on next page]

(54) **Title**: SOFT TISSUE CORING BIOPSY DEVICES AND METHODS

(57) **Abstract**: An excisional device may comprise a work element configured to rotate at a first rotation rate and comprising a first and a second articulable beak configured to cut tissue. A first helical element, configured to transport tissue cut by the first and second articulable beaks, may be co-axially disposed relative to the work element and operative to rotate at a second rotation rate that is different than the work element. A proximal sheath may be co-axially disposed relative to the work element and the first helical element, and may be configured to rotate the work element and to actuate the first and second articulable beaks.

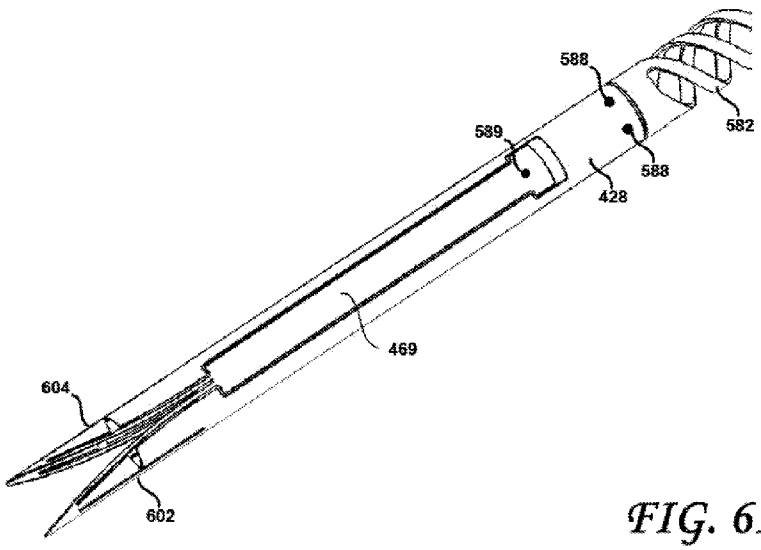


FIG. 61

WO 2014/193894 A3

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
25 June 2015

INTERNATIONAL SEARCH REPORT

14/039676 23.04.2015

International application No.
PCT/US 14/39676

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 10/02 (2015.01)
CPC - A61B 10/0275; A61B 10/06
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)
CPC: A61B 10/0275; A61B 10/06 IPC(8): A61B 10/02 (2015.01)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 600/567 (keyword limited; terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase; Google Patents; Google
Search Terms Used: jaw%, beak%, cutter%, living hinge, biopsy, excisional, mesh, tendon%, pull wire%, control wire%, inner, outer, open*, clos*, interior*, exterior*, blade%, cut*, rotat*, helical, spring

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0121153 A1 (TO) 13 May 2010 (13.05.2010) fig 3A-3E, para [0033], [0070]-[0072], [0121]-[0122]	1-7, 12, 14-19, 21
Y		20
A		8-11, 13
Y	US 2010/0078296 A1 (LAPEYRE et al) 01 April 2010 (01.04.2010) para [0024]	20

☐ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"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
07 April 2015 (07.04.2015)	23 APR 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 14/39676

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-21, directed to an excisional device with an articulable beak coupled to a body portion by a living hinge.

Group II: Claims 22-32 directed to an excisional device with a helical element formeed by selective removal of material from a proximal portion of a work element.

----Continued on Supplemental Page----

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-21

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Continuation of Box III: Observations where unity of invention is lacking

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I includes the special technical feature of a first articulable beak that is coupled to the body portion by a first living hinge, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a work element having a proximal portion defining a helical element, the helical element being formed by selective removal of material from the proximal portion of the work element and being configured to at least one of activate the first articulable beak to cut tissue and transport cut tissue, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an outer sheath:
a work element configured to fit at least partially within the outer sheath, the work element having proximal end and a first articulable beak at a distal end that is configured to cut tissue. However, these shared technical features do not represent a contribution over prior art as being anticipated by US5,762,069 A to Kelleher, et al. (hereinater 'Kelleher'), which teaches an outer sheath (104, fig 9a, 11):
a work element (88, 122a, 122b) configured to fit at least partially within the outer sheath, the work element having proximal end (88) and a first articulable beak (122a, 122b) at a distal end that is configured to cut tissue (fig 9a, 11, col 8, ln 47-51, col 9, ln 45-51).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.