US012594082B2

(12) **United States Patent**
Sidebotham et al.

(10) **Patent No.: US 12,594,082 B2**
(45) **Date of Patent: Apr. 7, 2026**

(54) **SURGICAL CUTTING TOOL**

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(72) Inventors: **Christopher G. Sidebotham**, Mendham, NJ (US); **Leon Roitburg**, East Hanover, NJ (US); **Randall J. Lewis**, Bethesda, MD (US)

(73) Assignee: **LRS Science and Technology, LLC**, Mendham, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 223 days.

(21) Appl. No.: **18/302,295**

(22) Filed: **Apr. 18, 2023**

(65) **Prior Publication Data**

US 2023/0255648 A1 Aug. 17, 2023

Related U.S. Application Data

(63) Continuation of application No. PCT/US2021/054429, filed on Oct. 11, 2021.

(60) Provisional application No. 63/093,717, filed on Oct. 19, 2020.

(51) **Int. Cl.**
A61B 17/16 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 17/1666*** (2013.01); *A61B 2017/00526* (2013.01)

(58) **Field of Classification Search**
CPC A61B 17/1666
See application file for complete search history.

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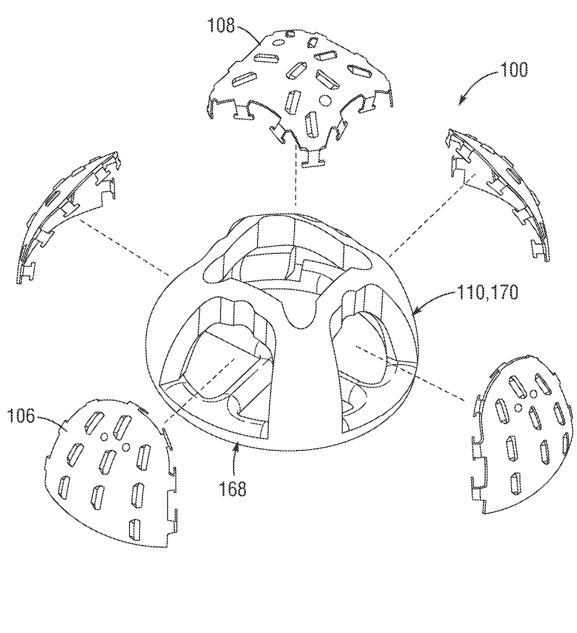
Primary Examiner — Andrew Yang
(74) *Attorney, Agent, or Firm* — Klarquist Sparkman, LLP

(57) **ABSTRACT**

A hemispherical cutting tool has a frame having a first end portion and a second end portion. Curved side panels are coupled to the frame and arranged about the rotational axis of the cutting tool, and have cutting teeth and engagement members extending inwardly into the frame from edge portions of the curved side panels in a direction toward a hollow interior of the hemispherical cutting tool. A dome panel is coupled to the second end portion of the frame such that the cutting tool has a hemispherical shape, the dome panel comprising cutting teeth and a plurality of engagement members extending inwardly into the frame in a direction toward the hollow interior of the tool. The frame is injection molded around the curved side panels and the dome panel such that the engagement members of the curved side panels and the dome panel are embedded in the frame.

24 Claims, 31 Drawing Sheets



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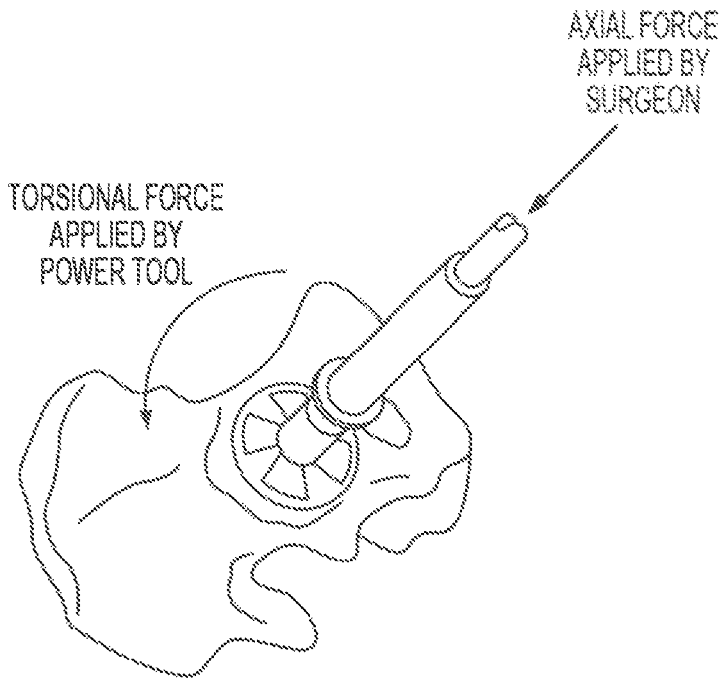

AXIAL FORCE APPLIED BY SURGEON
TORSIONAL FORCE APPLIED BY POWER TOOL

FIG. 1

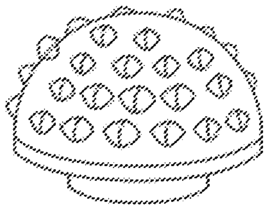


FIG. 2A

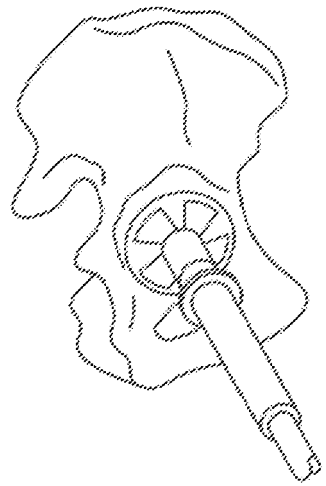


FIG. 2B

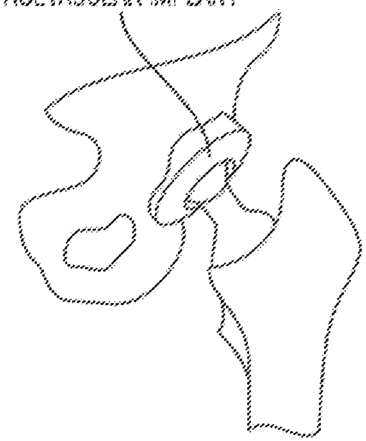


FIG. 2C

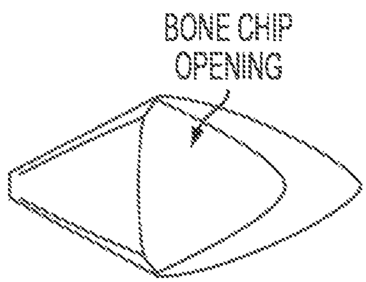


FIG. 3B

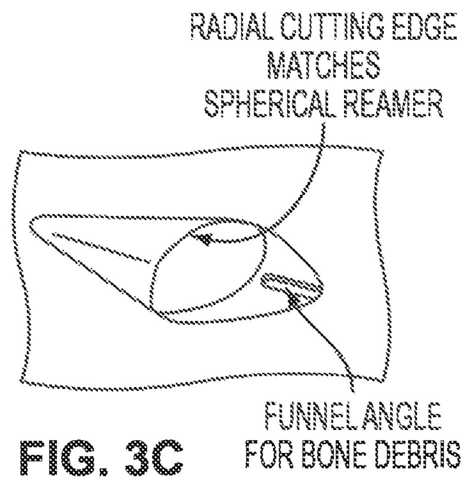


FIG. 3C

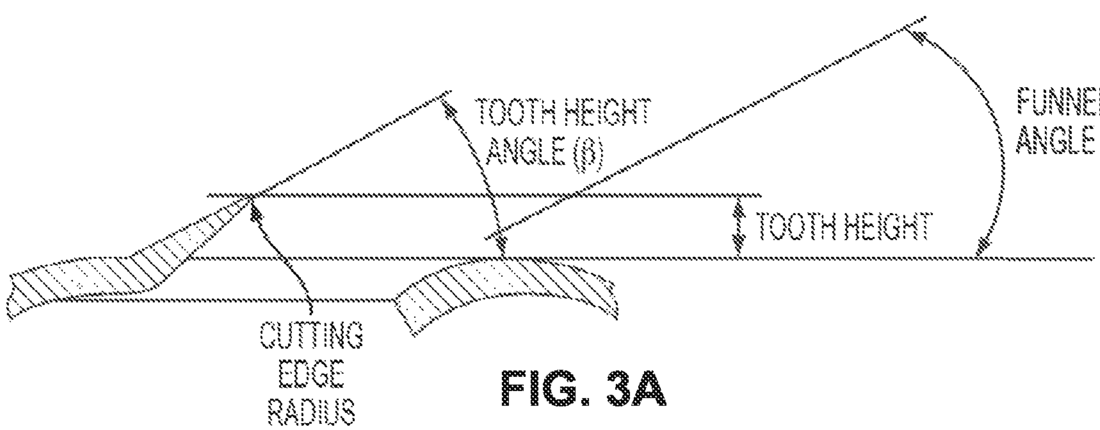


FIG. 3A

FIG. 4A

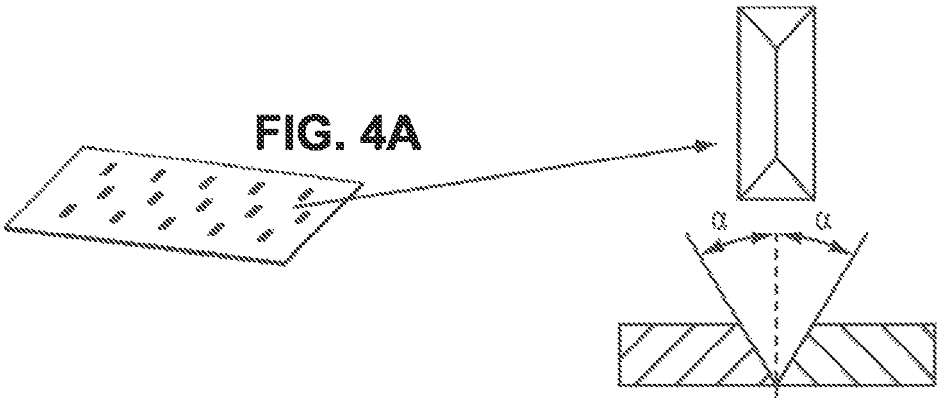


FIG. 4B

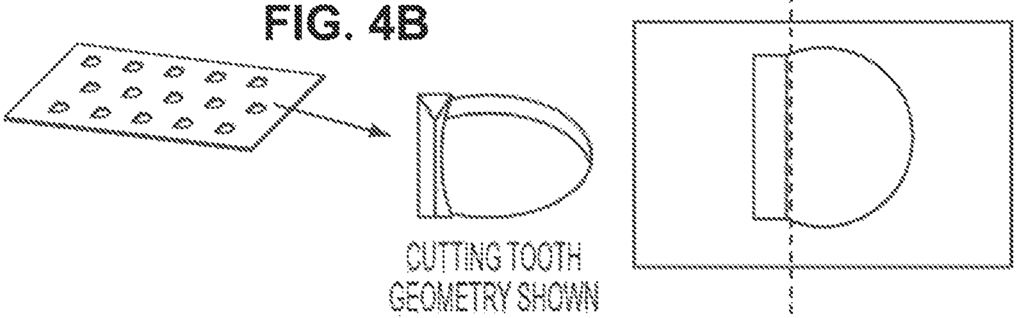
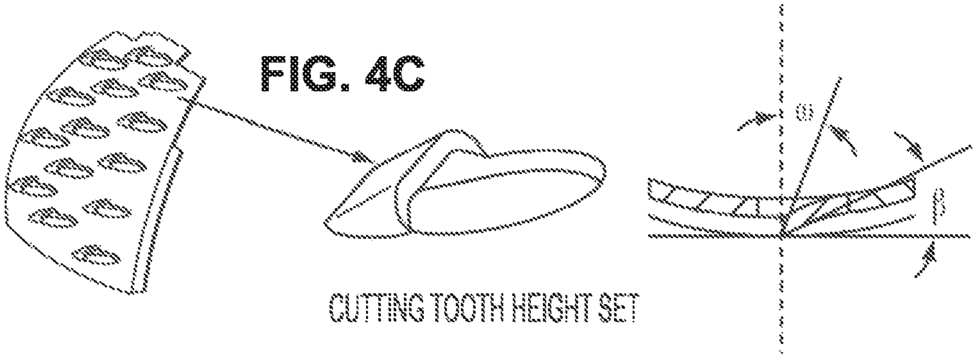


FIG. 4C



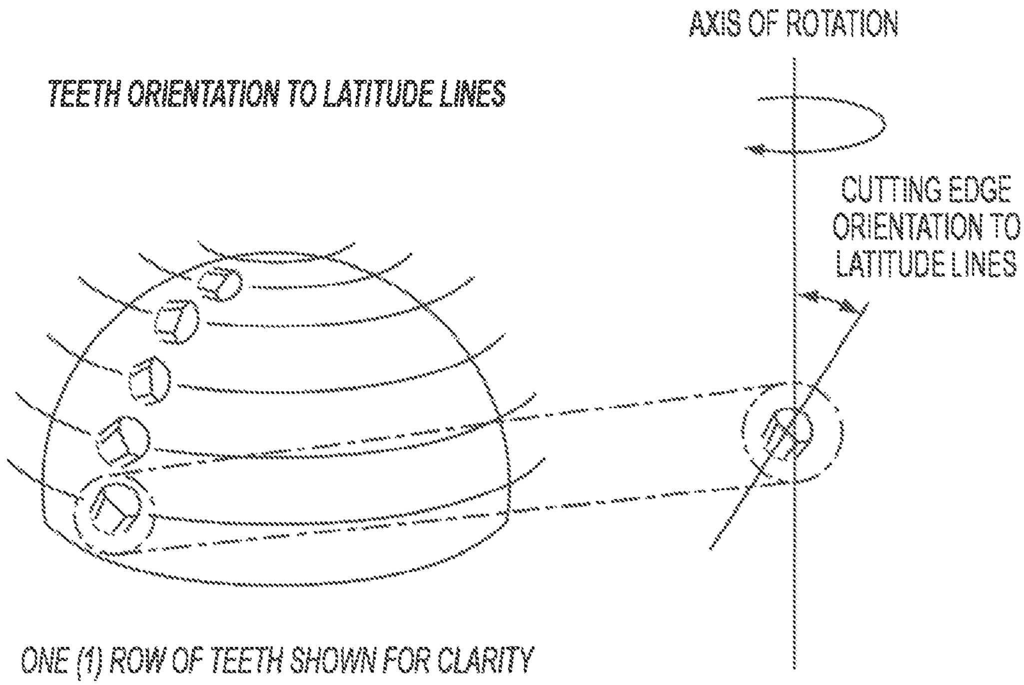

AXIS OF ROTATION
TEETH ORIENTATION TO LATITUDE LINES
CUTTING EDGE ORIENTATION TO LATITUDE LINES
ONE (1) ROW OF TEETH SHOWN FOR CLARITY

FIG. 5A FIG. 5B

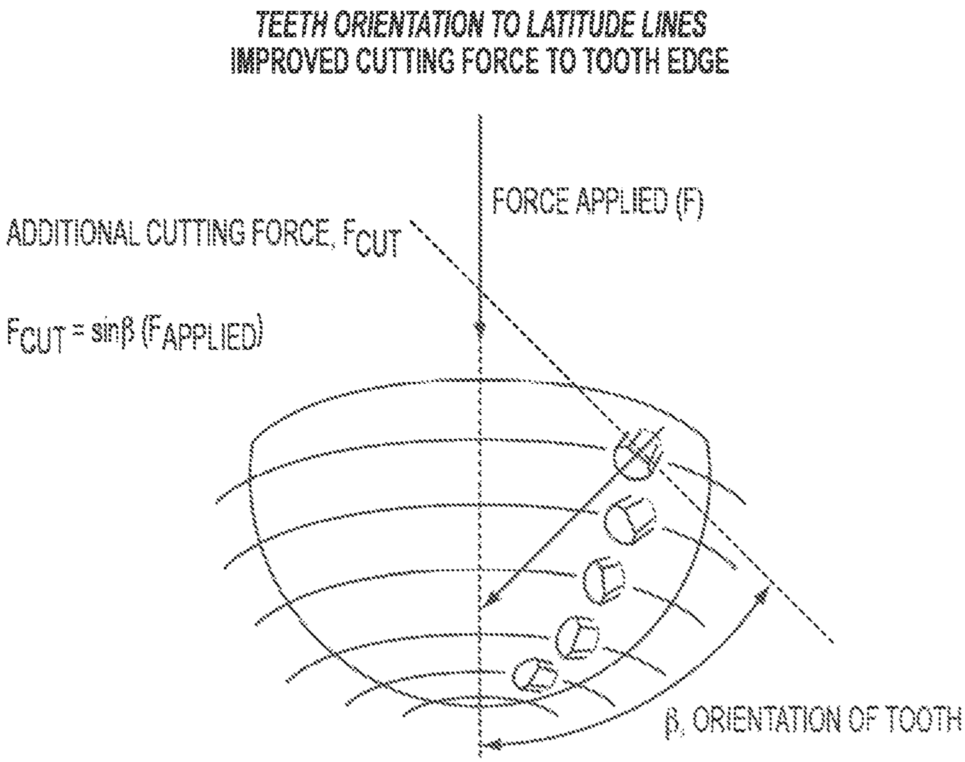

TEETH ORIENTATION TO LATITUDE LINES
IMPROVED CUTTING FORCE TO TOOTH EDGE
FORCE APPLIED (F)
ADDITIONAL CUTTING FORCE, F_{CUT}
$F_{CUT} = \sin\beta (F_{APPLIED})$
β, ORIENTATION OF TOOTH

FIG. 6

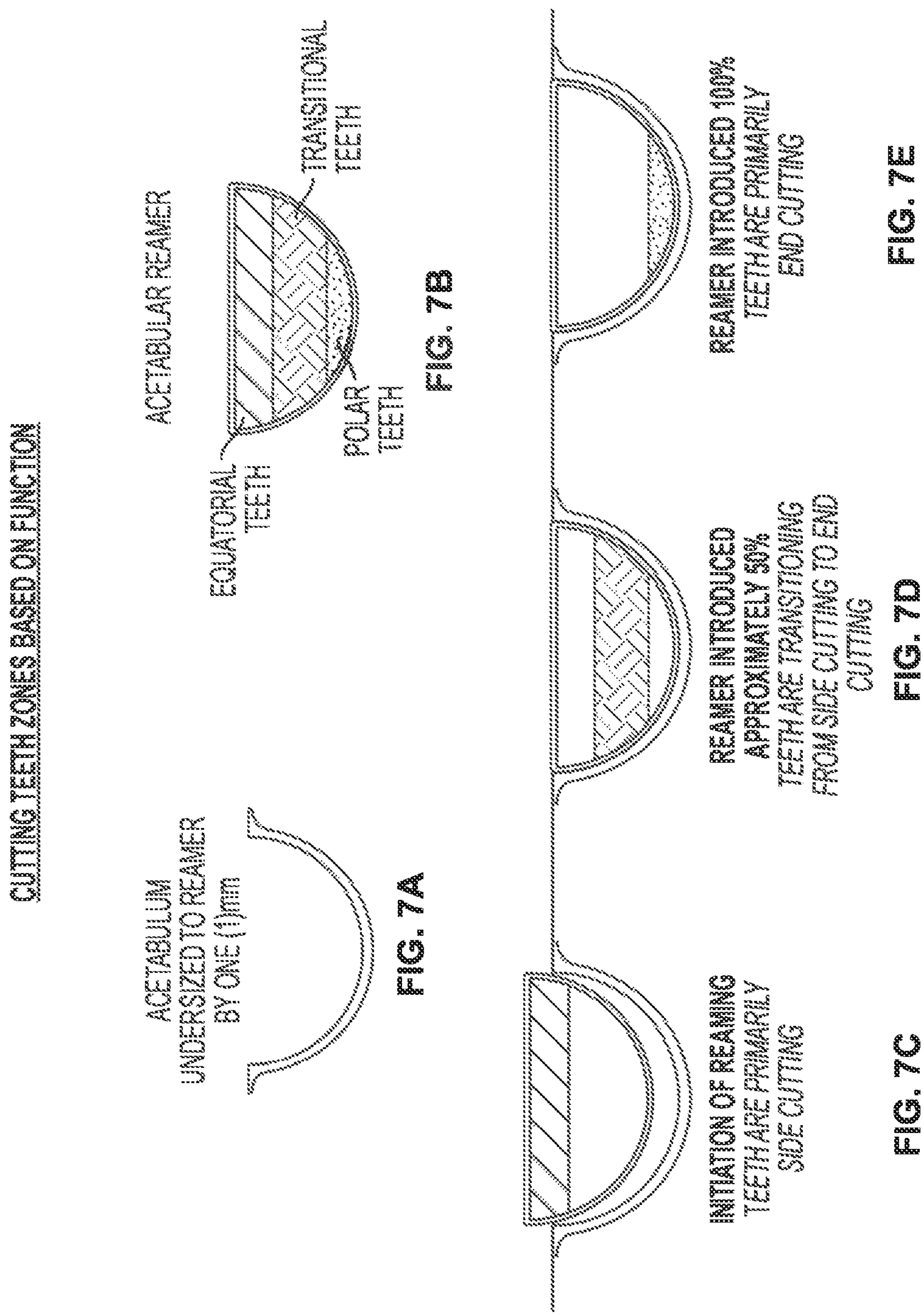


FIG. 7A

FIG. 7B

FIG. 7C

FIG. 7D

FIG. 7E

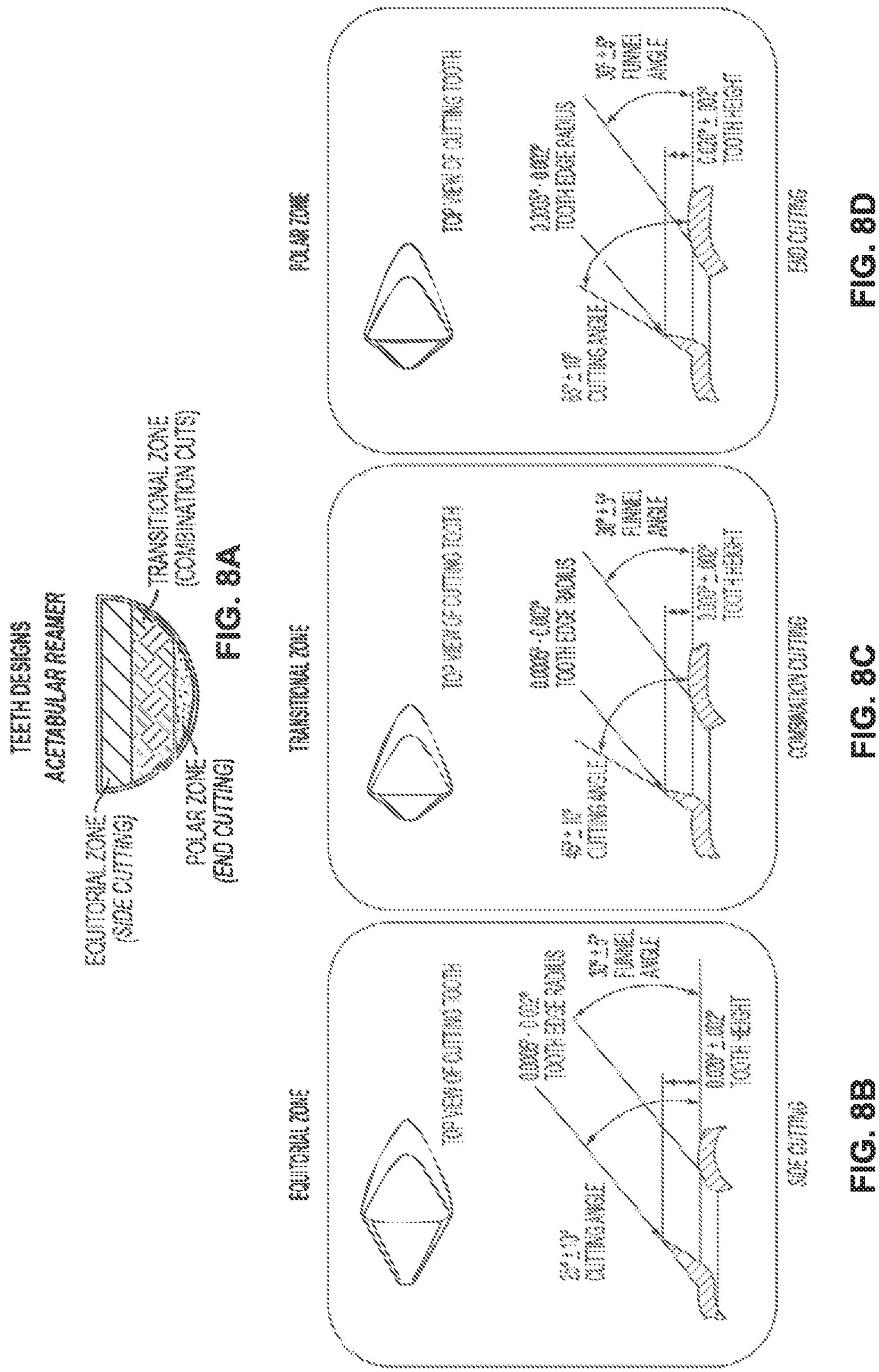


FIG. 8A

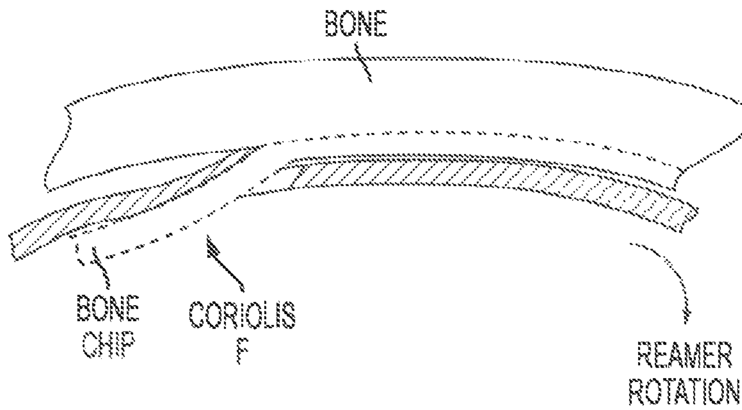
FIG. 8B

FIG. 8C

FIG. 8D

CUTTING BONE

FRICTION-HEAT ASSOCIATED WITH BONE CHIP



Fc = -2mΩ (v) WHERE,

m = MASS OF THE REAMER
Ω = ANGULAR VELOCITY VECTOR
v = VELOCITY OF ROTATING SYSTEM

FIG. 9

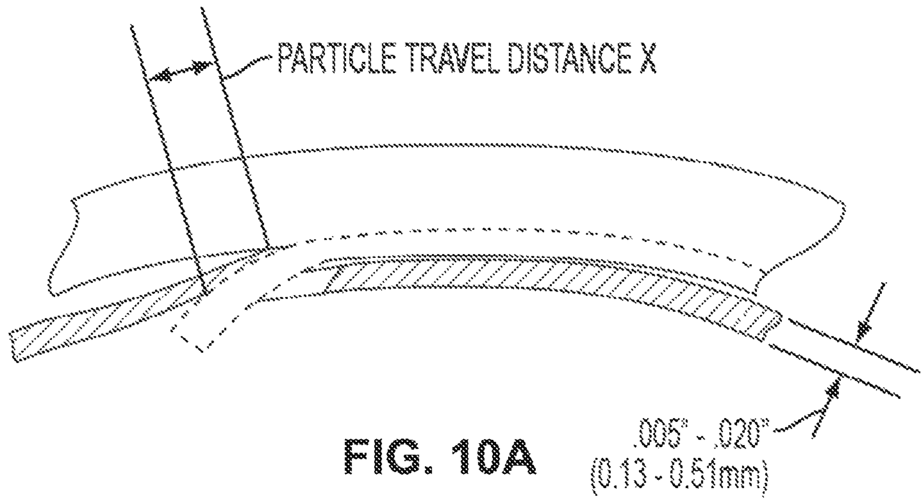


FIG. 10A

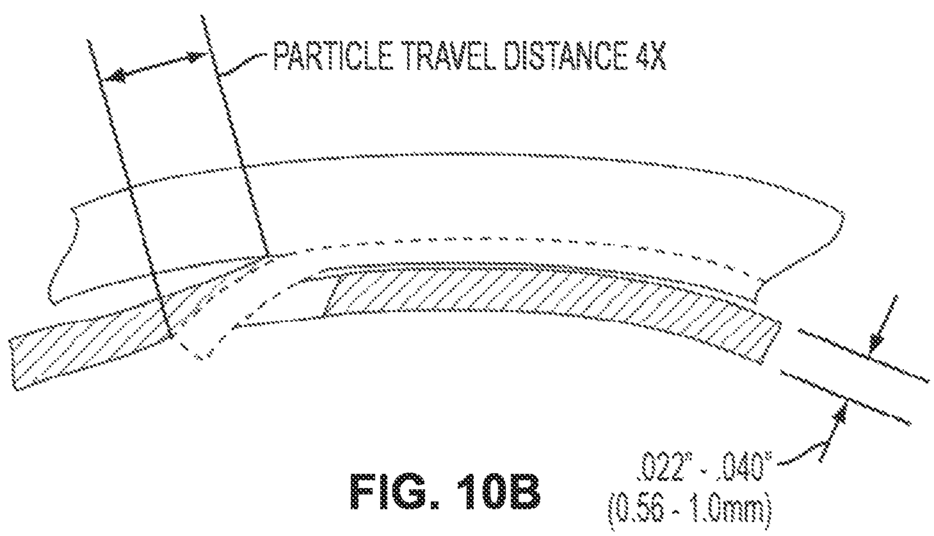
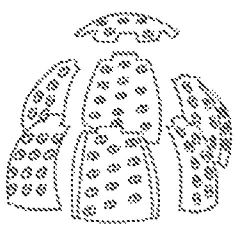
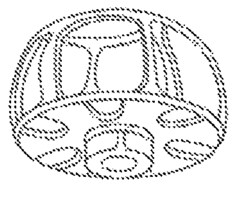


FIG. 10B



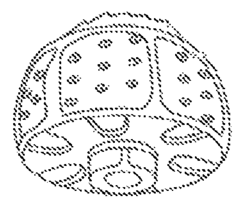
STAMPED CUTTING PANELS

FIG. 11A



INJECTION MOLDING TOOL CREATES PLASTIC FRAME AROUND PANELS

FIG. 11B



FINISHED REAMER IS STRUCTURALLY SOUND THROUGH THE FRAME AND MAINTAINS CUTTER SPHERICITY AND TOLERANCES WITHIN .004"

FIG. 11C

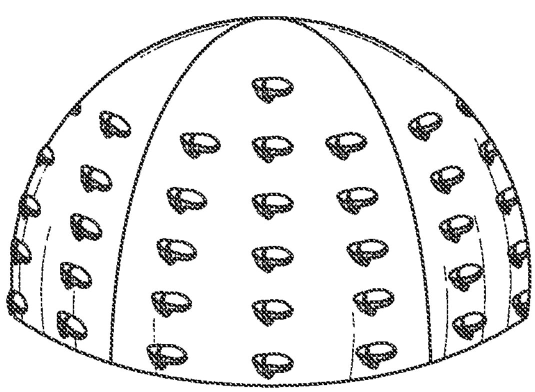


FIG. 12

Hollow Spherical Reamers:

Acetabulum Preparation

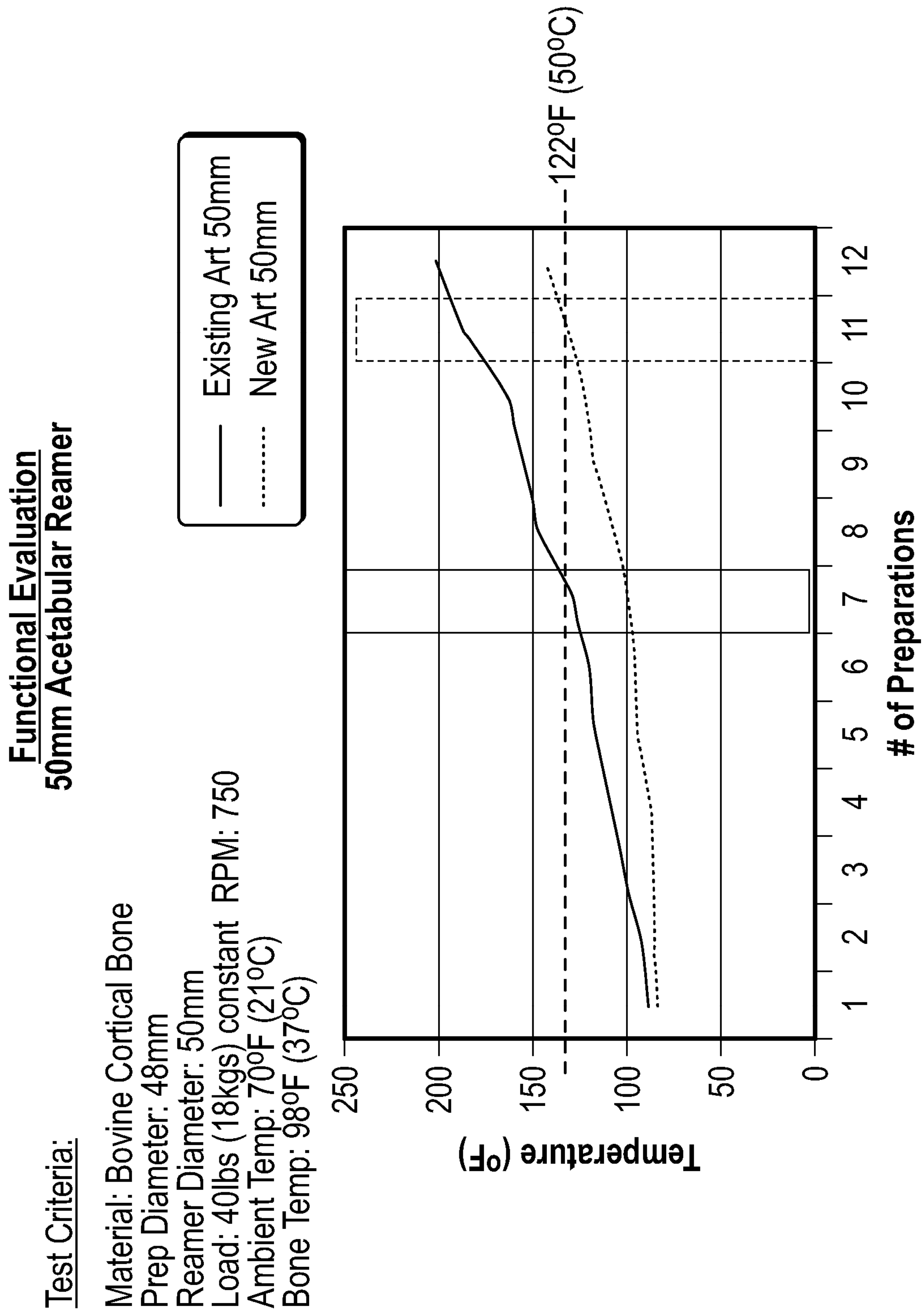

Functional Evaluation
50mm Acetabular Reamer
Test Criteria:
Material: Bovine Cortical Bone
Prep Diameter: 48mm
Reamer Diameter: 50mm
Load: 40lbs (18kgs) constant RPM: 750
Ambient Temp: 70°F (21°C)
Bone Temp: 98°F (37°C)
Existing Art 50mm
New Art 50mm
122°F (50°C)
Temperature (°F)
250
200
150
100
50
0
1
2
3
4
5
6
7
8
9
10
11
12
# of Preparations

FIG. 13

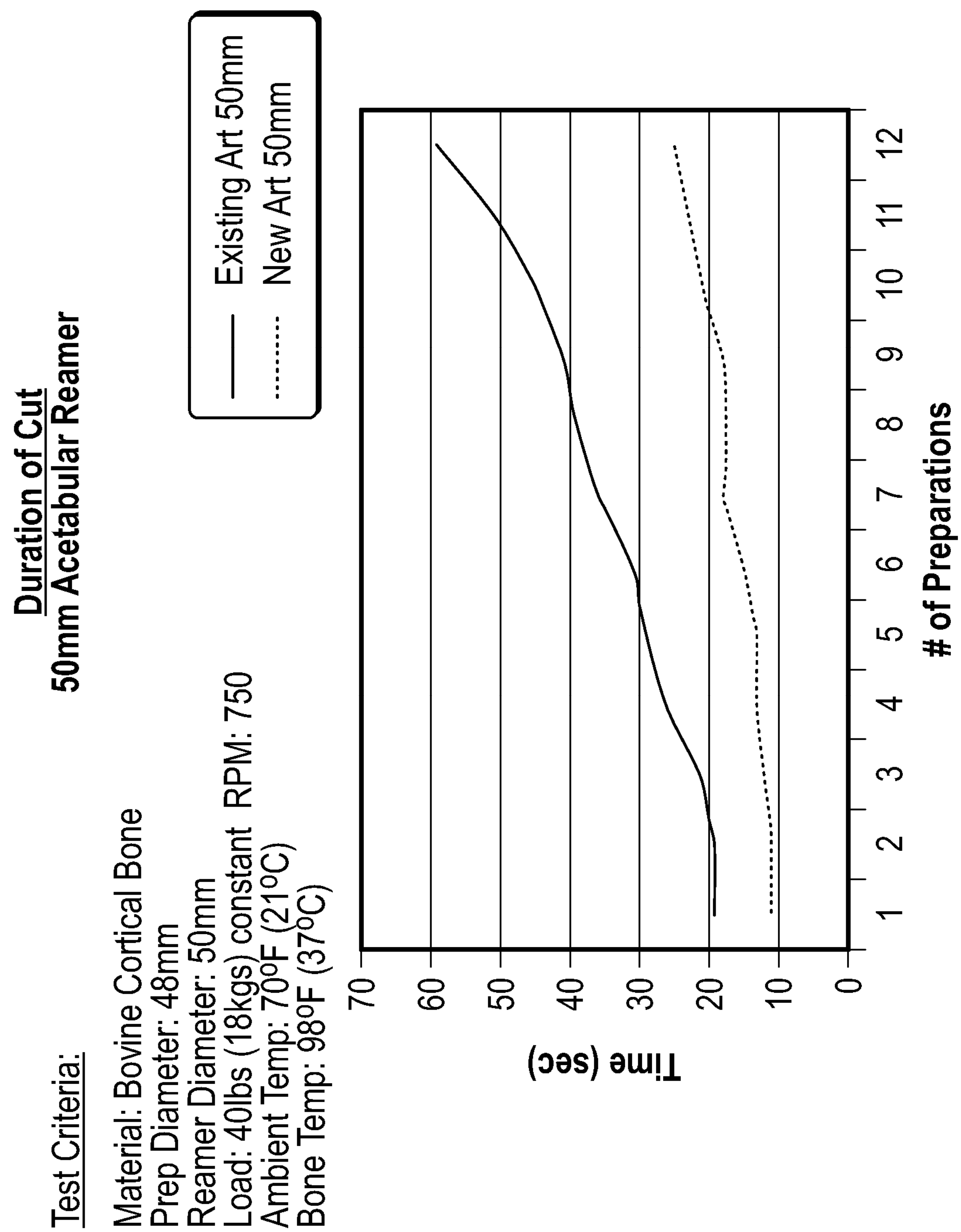

Duration of Cut
50mm Acetabular Reamer
Test Criteria:
Material: Bovine Cortical Bone
Prep Diameter: 48mm
Reamer Diameter: 50mm
Load: 40lbs (18kgs) constant RPM: 750
Ambient Temp: 70°F (21°C)
Bone Temp: 98°F (37°C)
Existing Art 50mm
New Art 50mm
Time (sec)
0
10
20
30
40
50
60
70
1
2
3
4
5
6
7
8
9
10
11
12
# of Preparations

FIG. 14

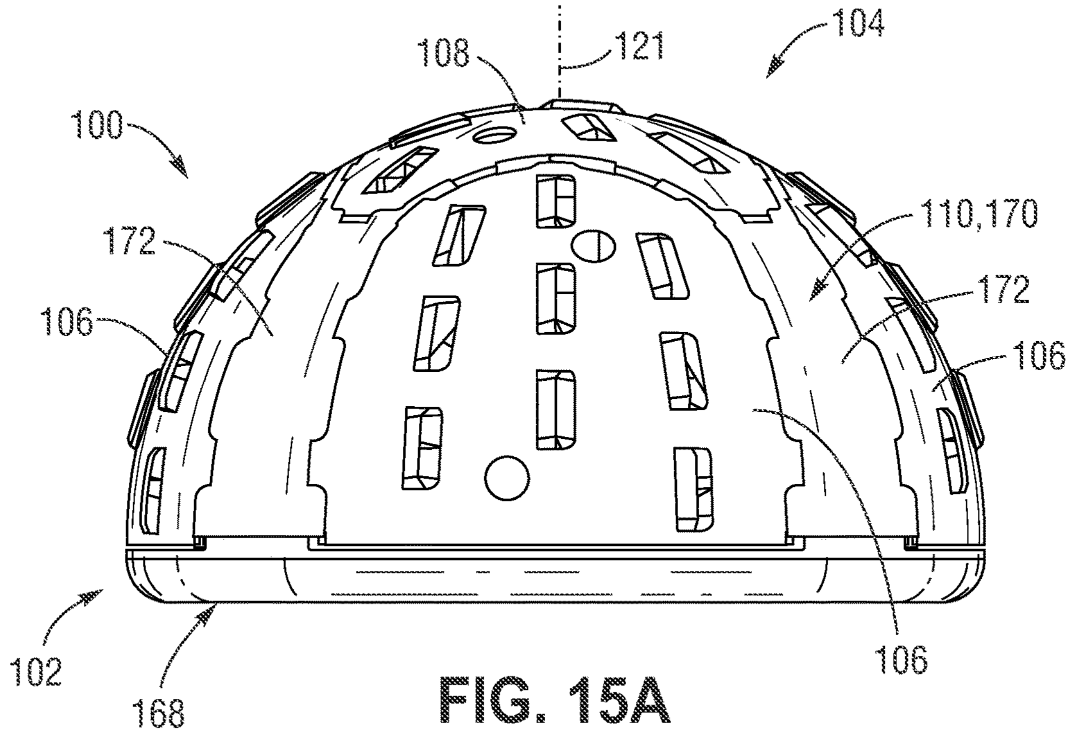


FIG. 15A

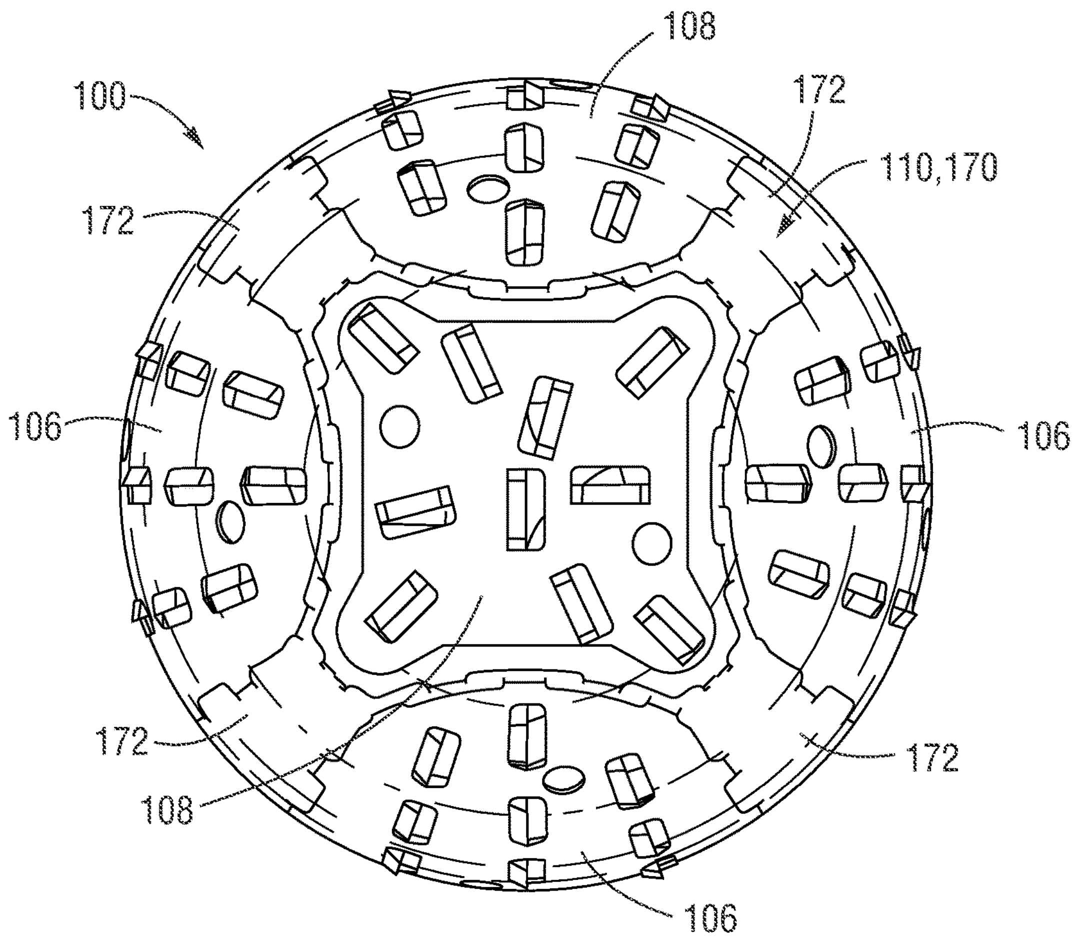


FIG. 15B

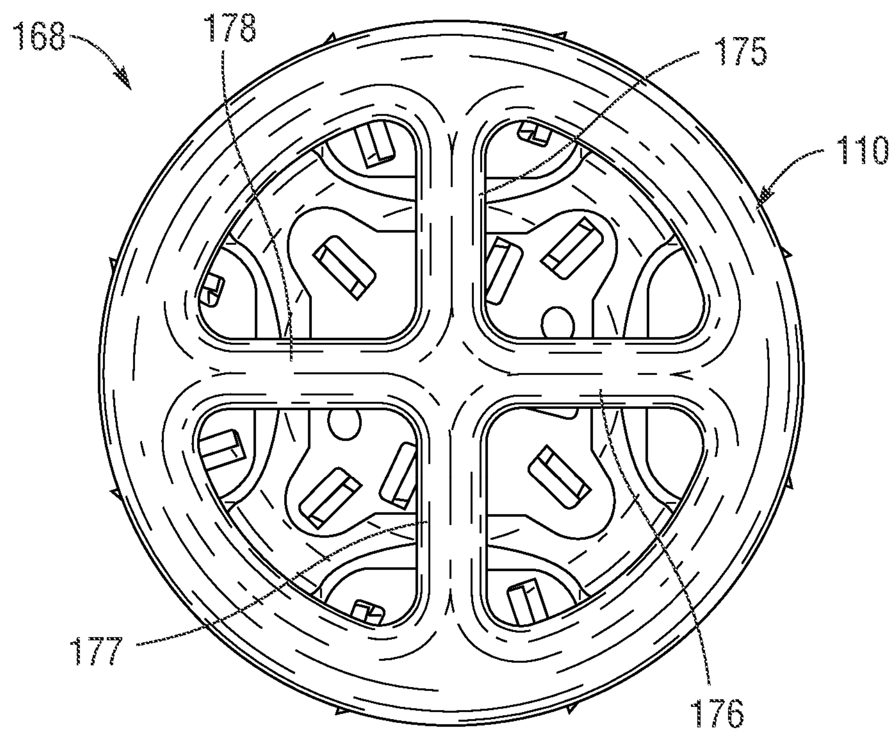


FIG. 15C

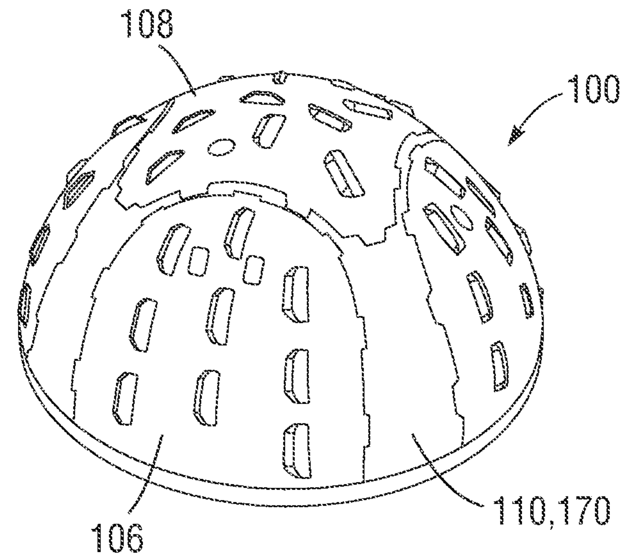


FIG. 15D

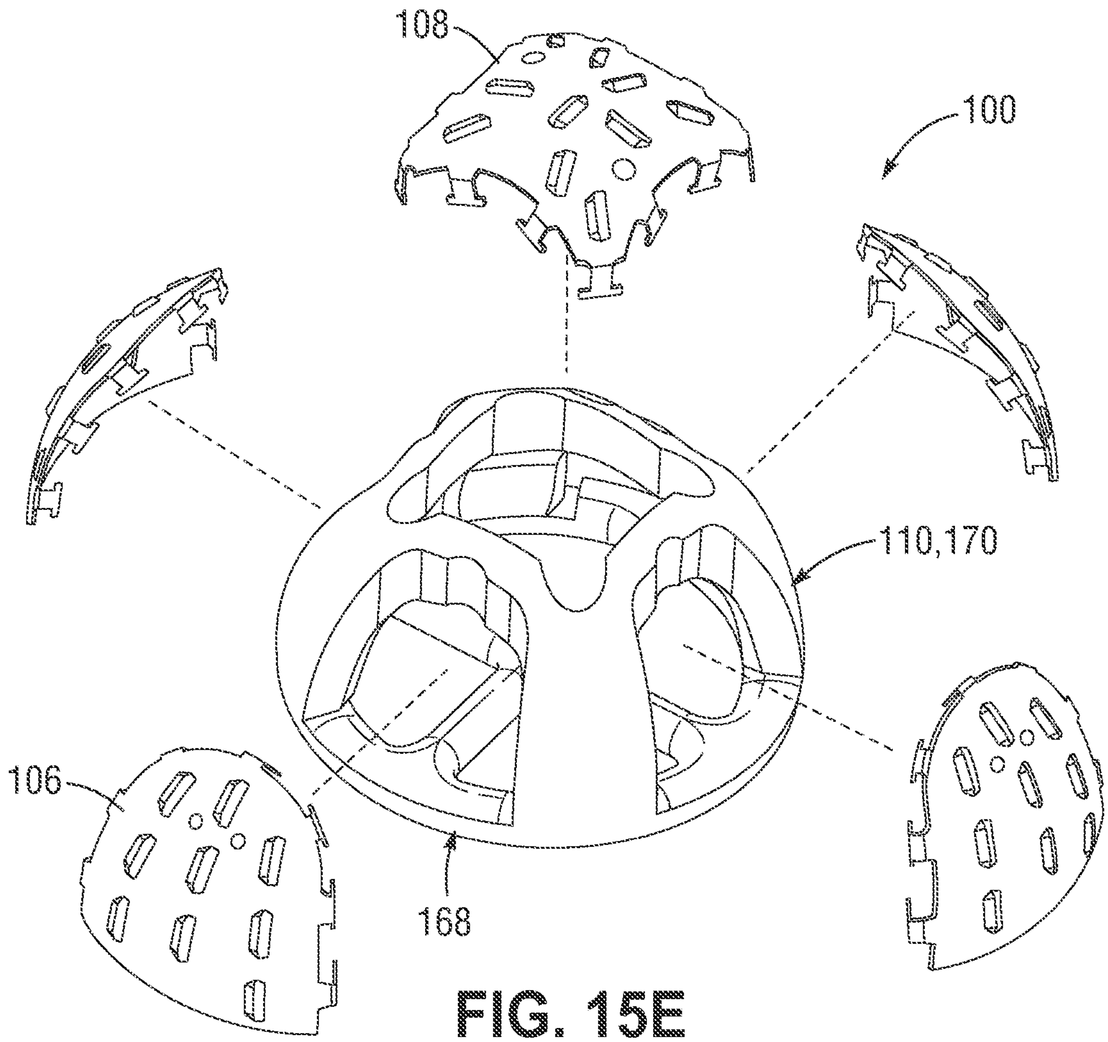


FIG. 15E

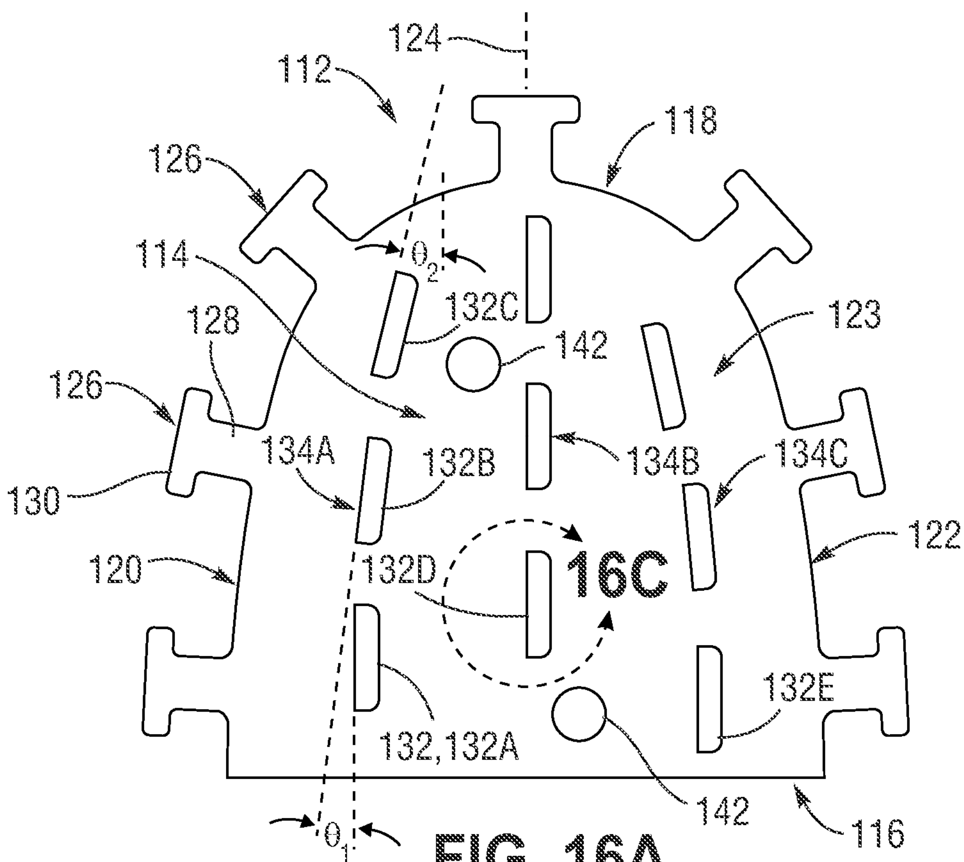

124
112
118
126
114
θ2
132C
123
128
142
126
134A
132B
134B
134C
130
122
120
132D
16C
132E
132,132A
142
116
θ1

FIG. 16A

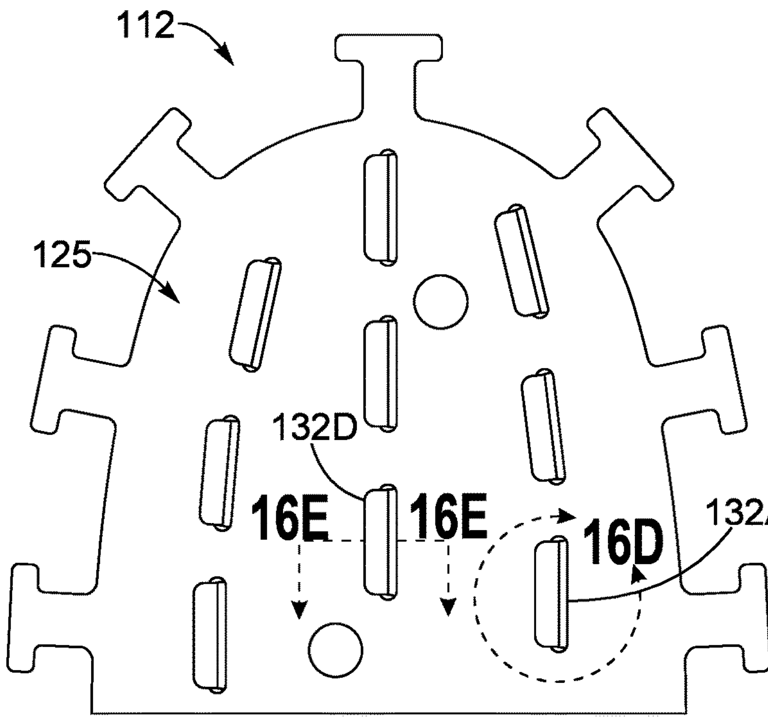


FIG. 16B

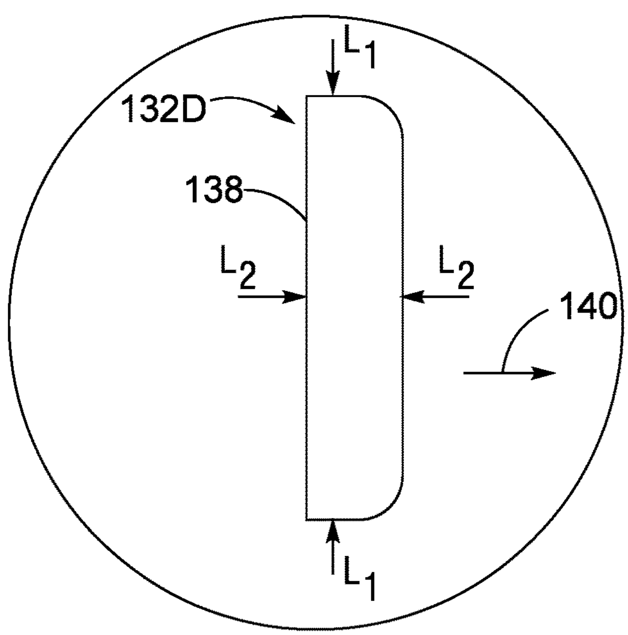


FIG. 16C

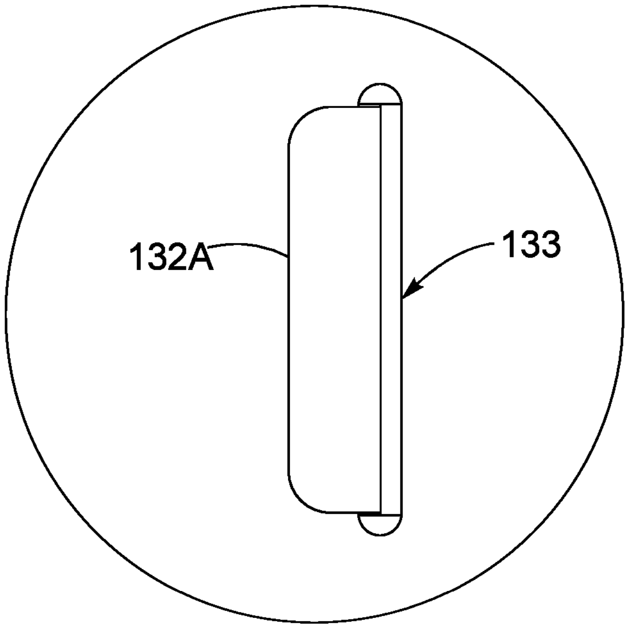


FIG. 16D

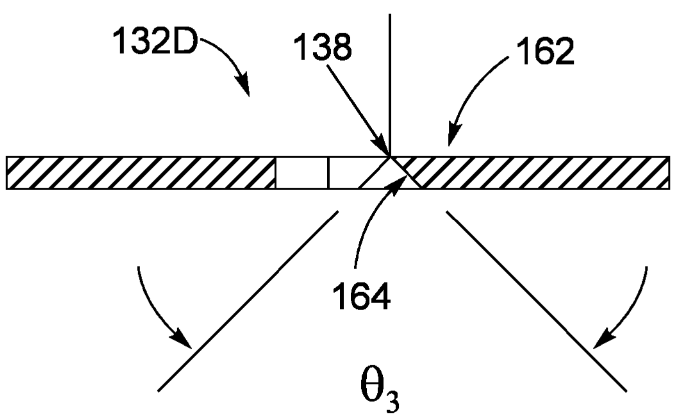


FIG. 16E

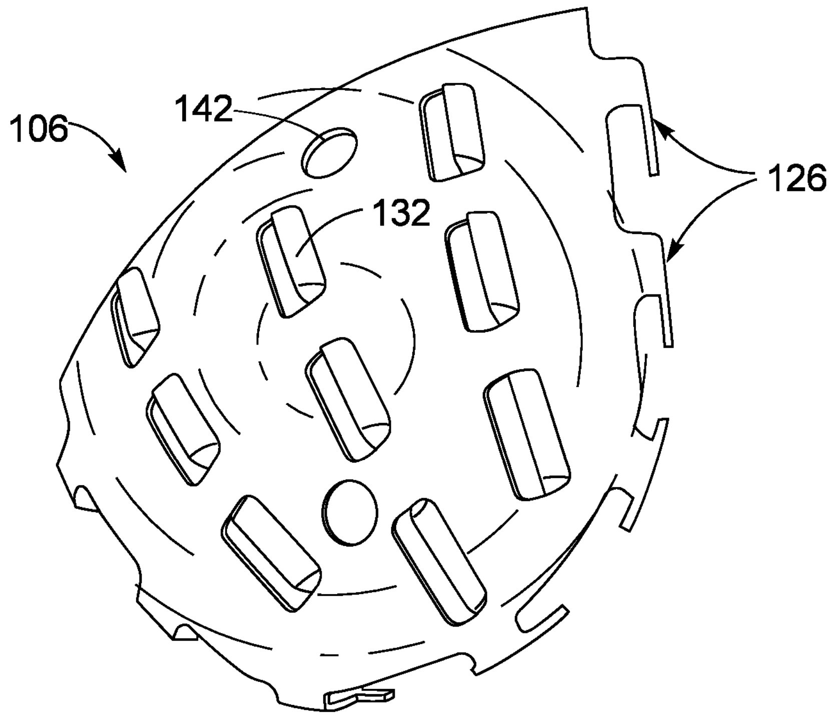


FIG. 17

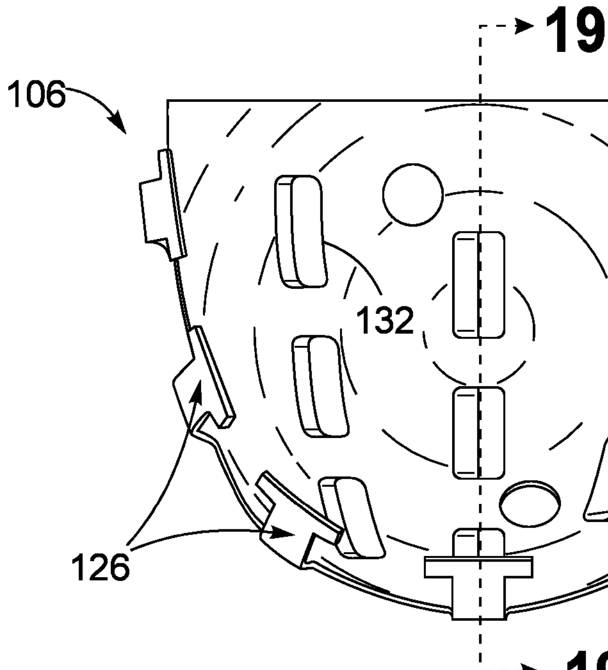


FIG. 18

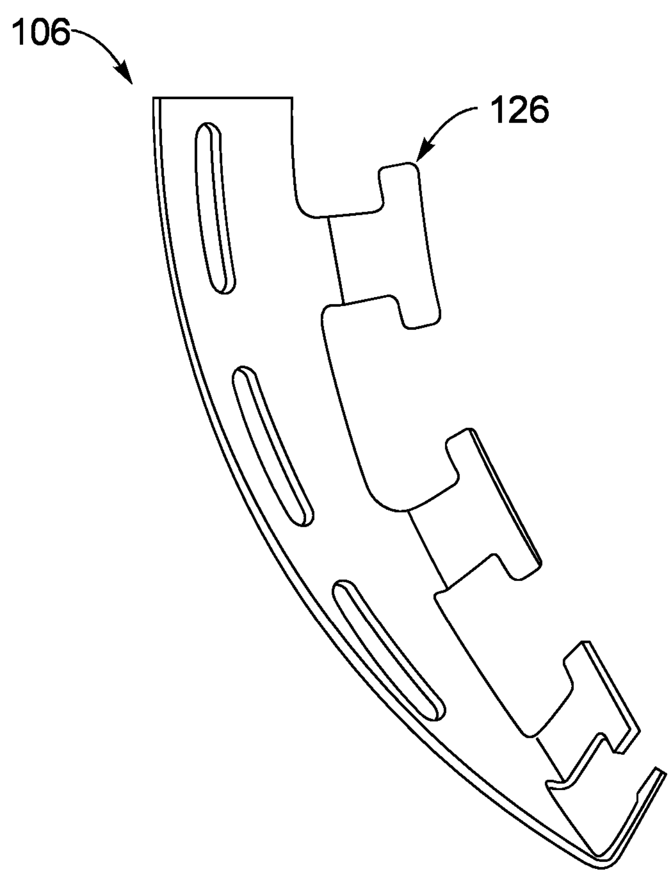


FIG. 19

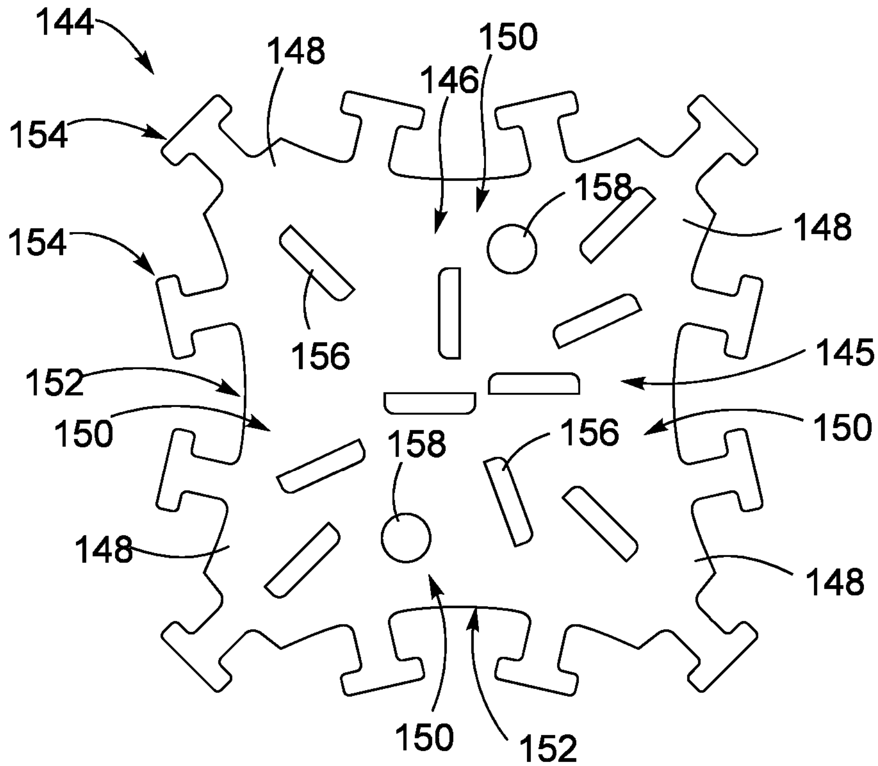


FIG. 20A

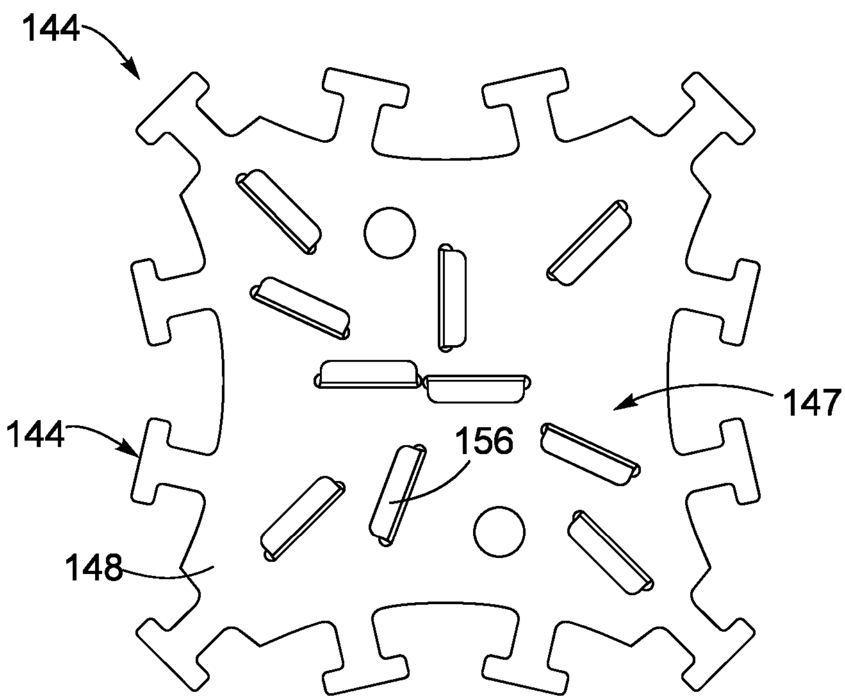


FIG. 20B

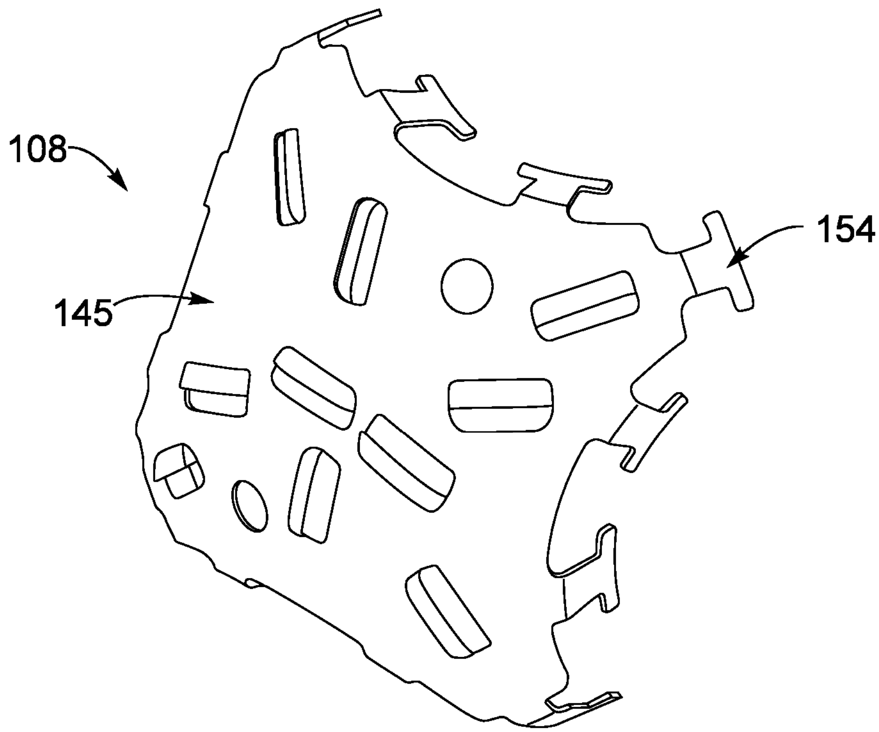


FIG. 21A

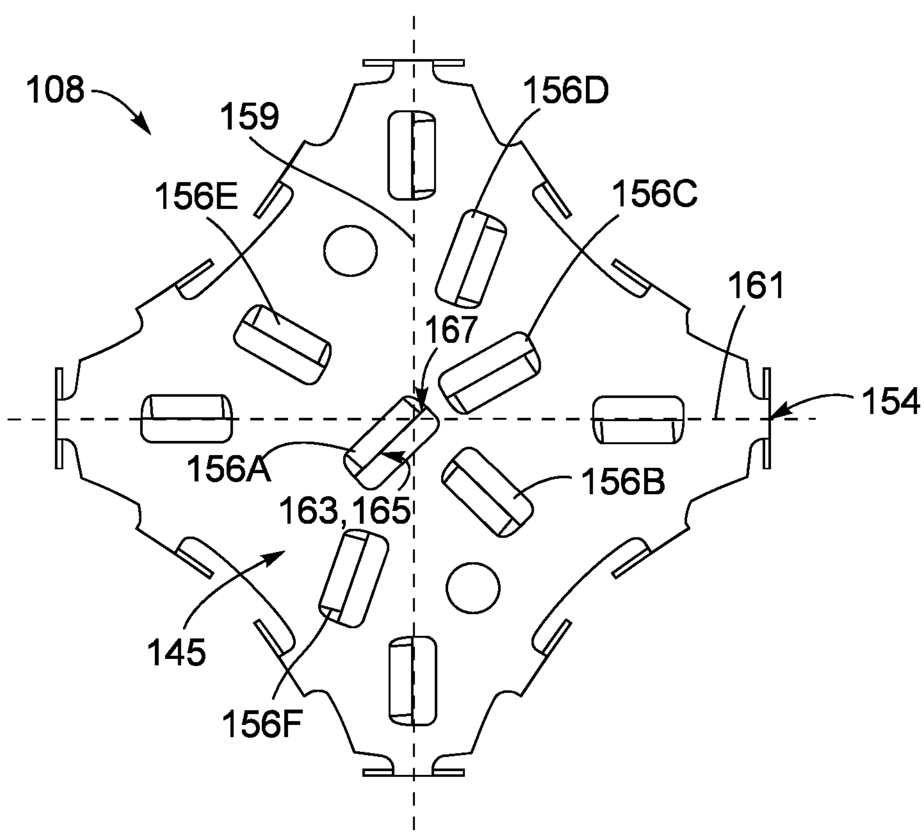


FIG. 21B

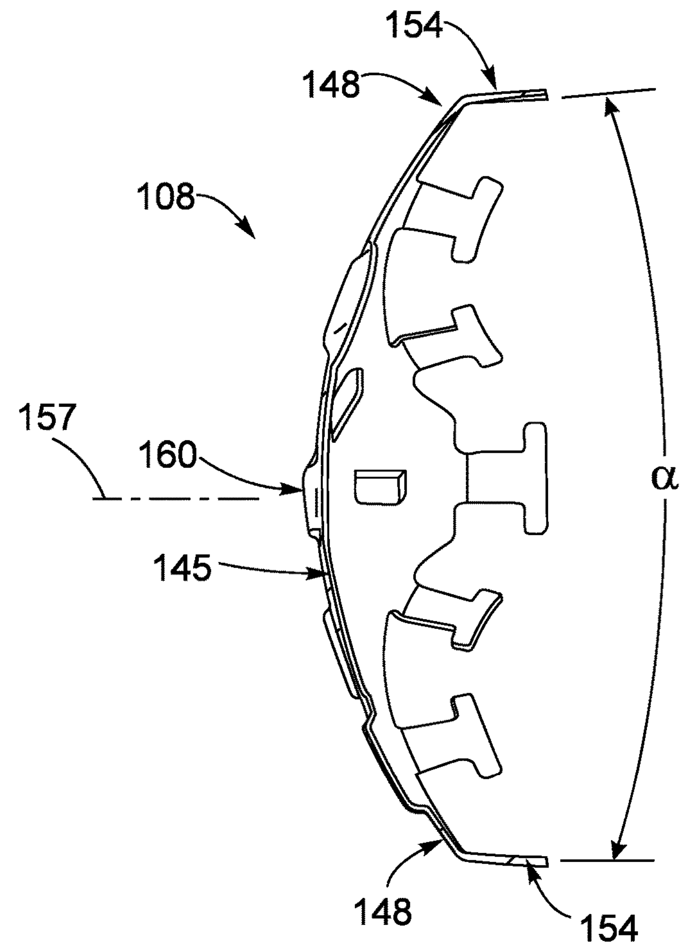


FIG. 21C

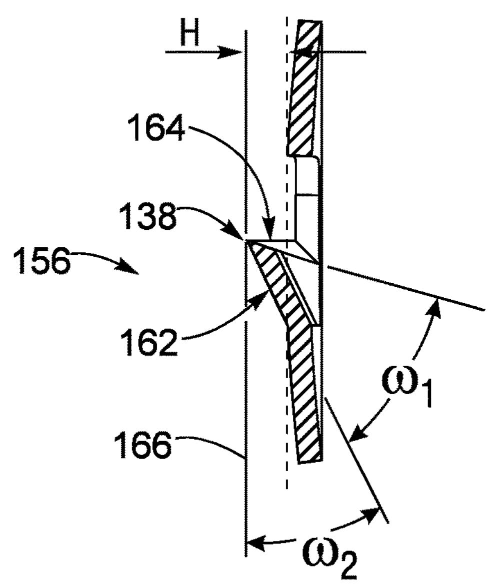


FIG. 22B

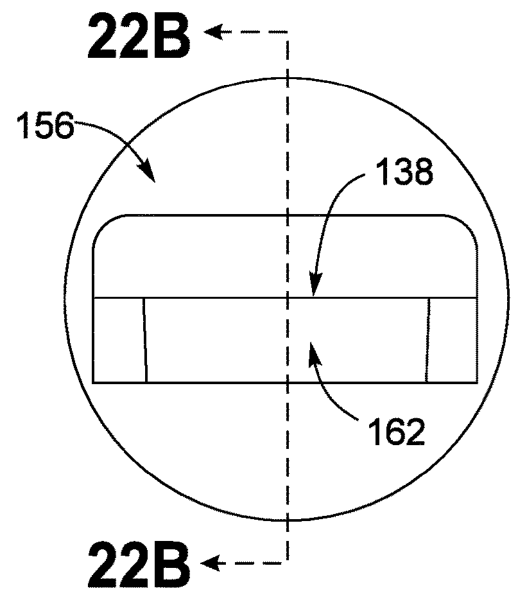


FIG. 22A

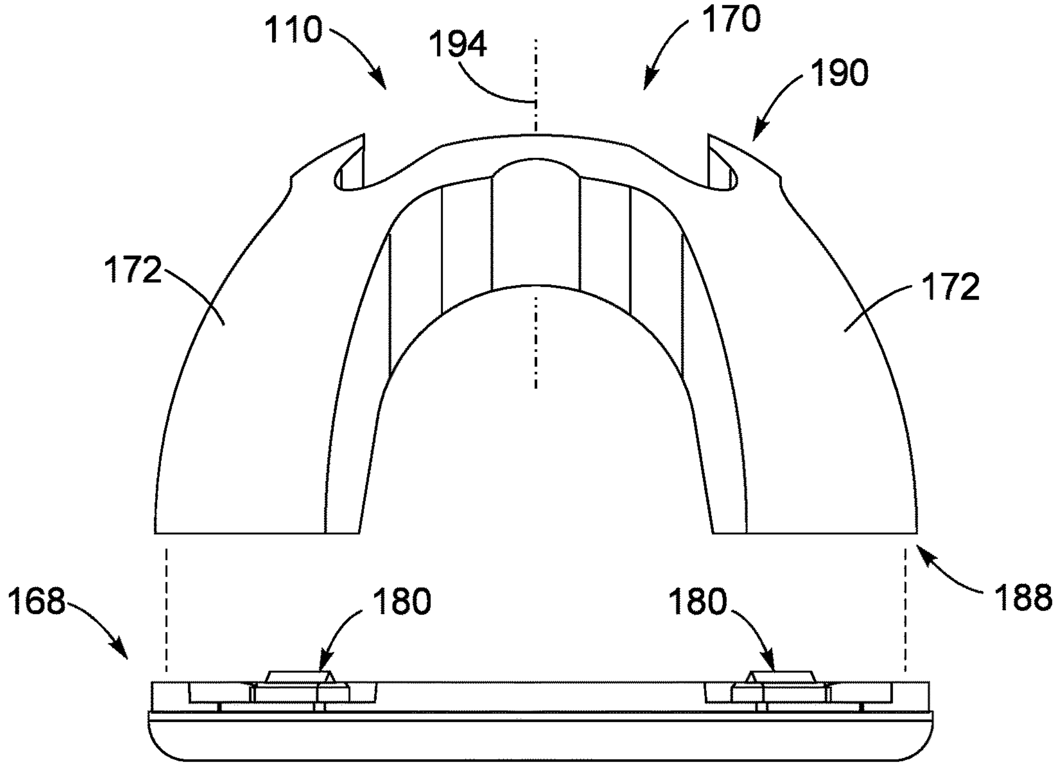


FIG. 23

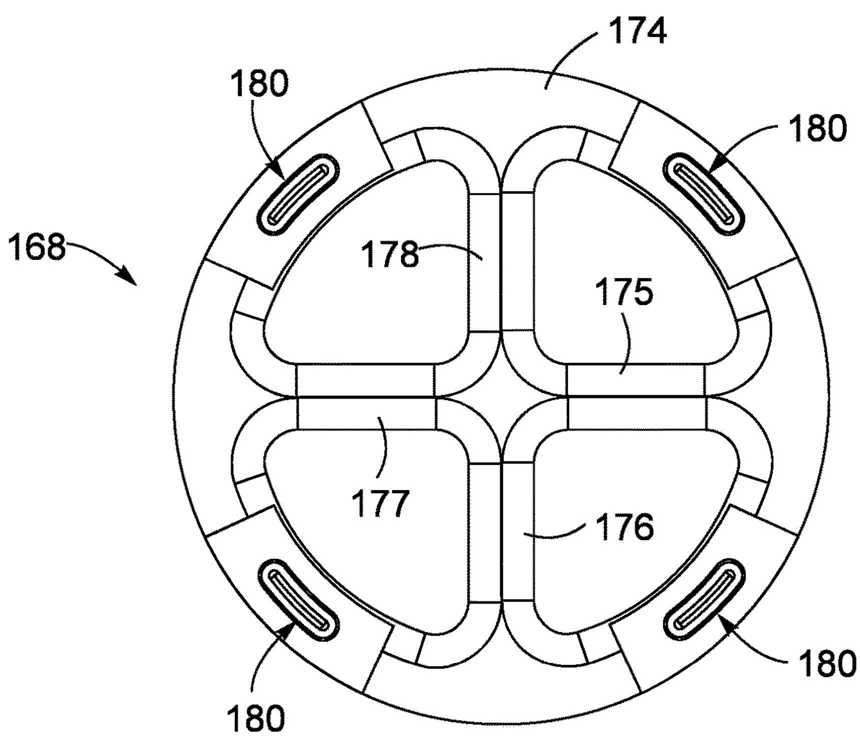


FIG. 24A

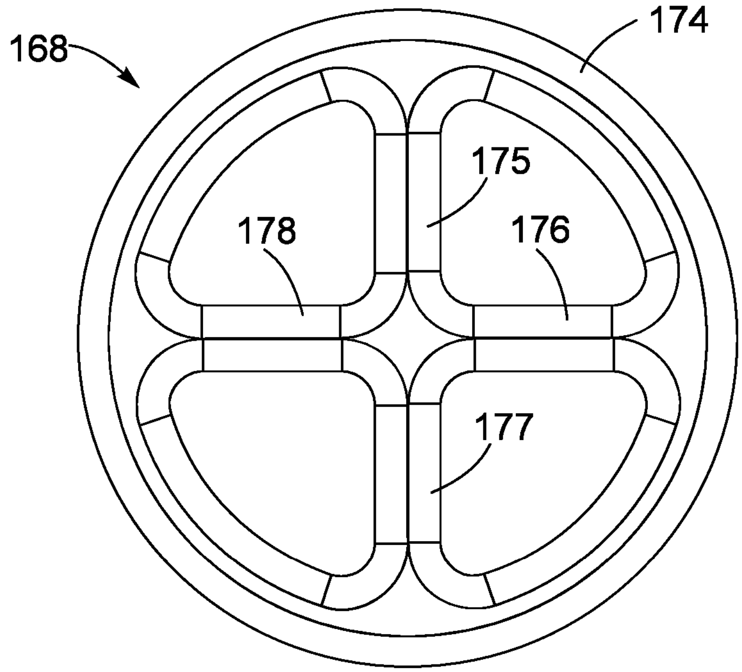


FIG. 24B

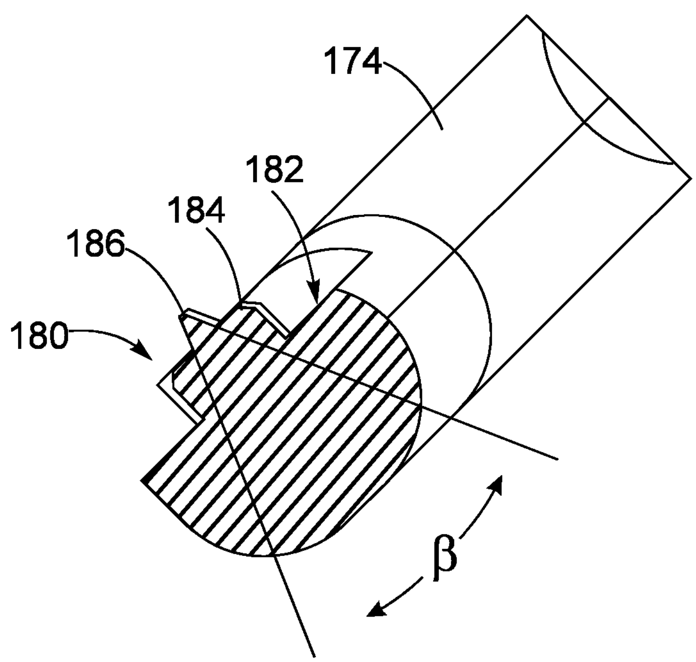


FIG. 25

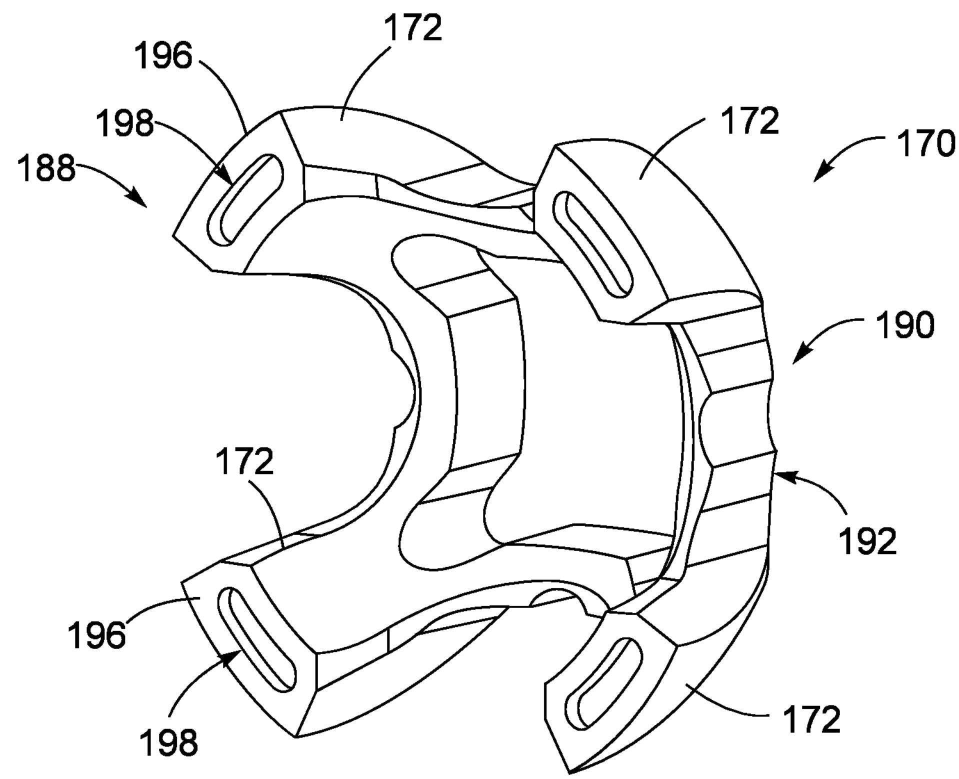

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FIG. 26

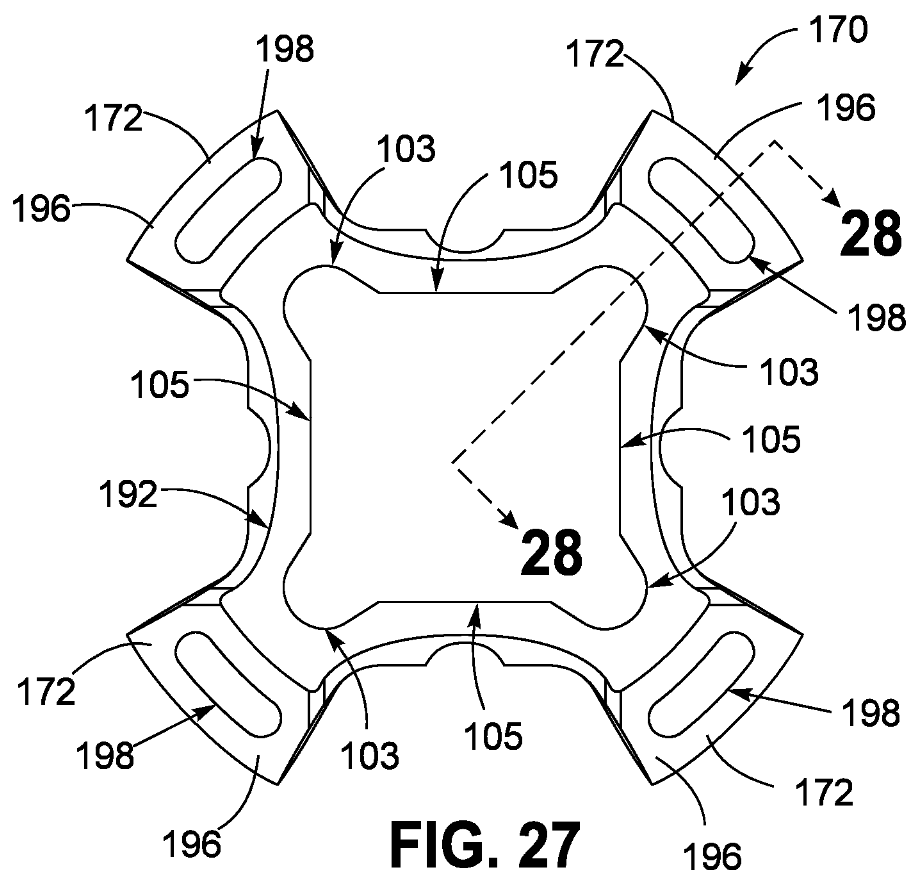
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FIG. 27

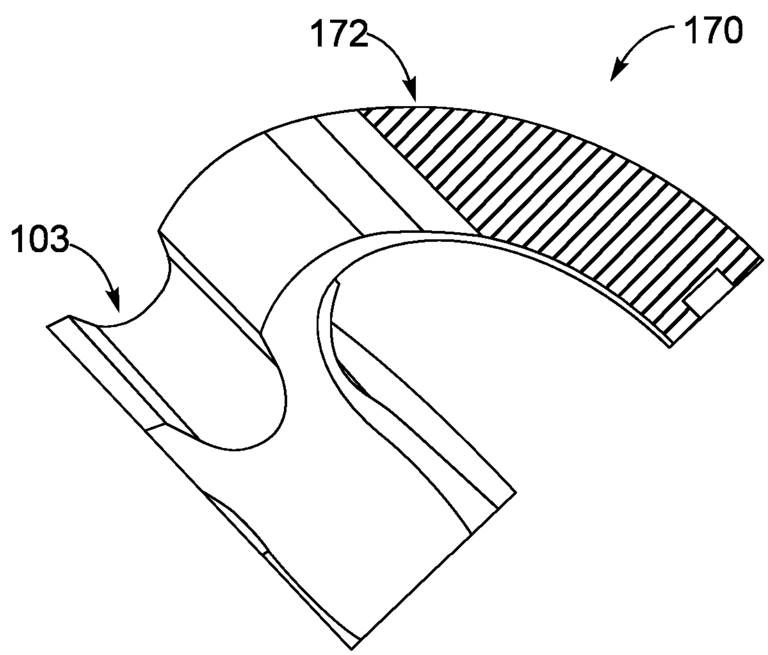

FIG. 28

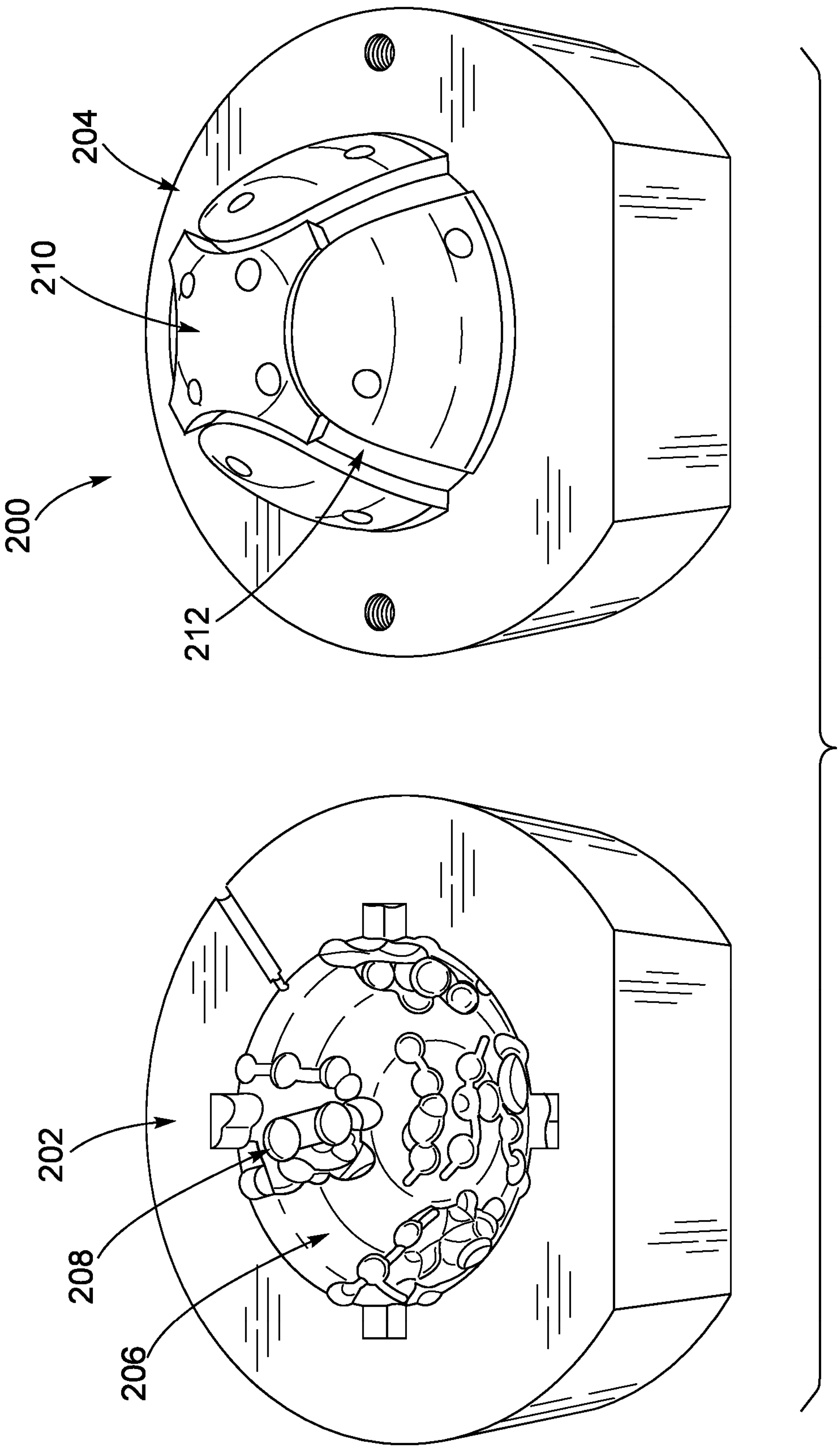

FIG. 29

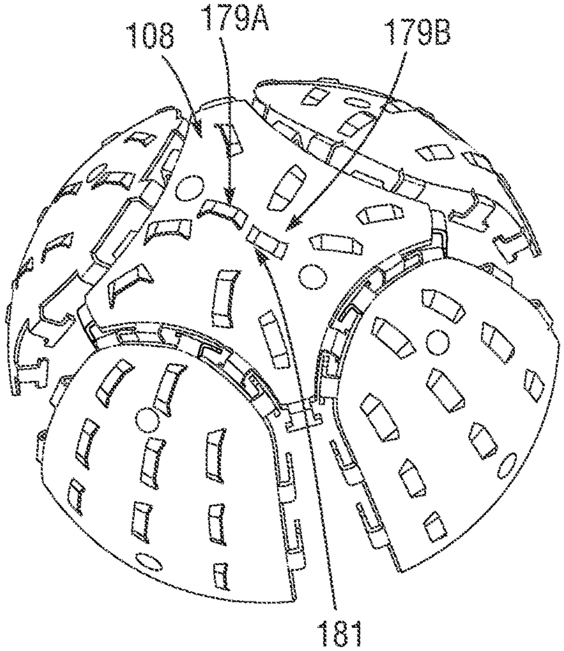

FIG. 30

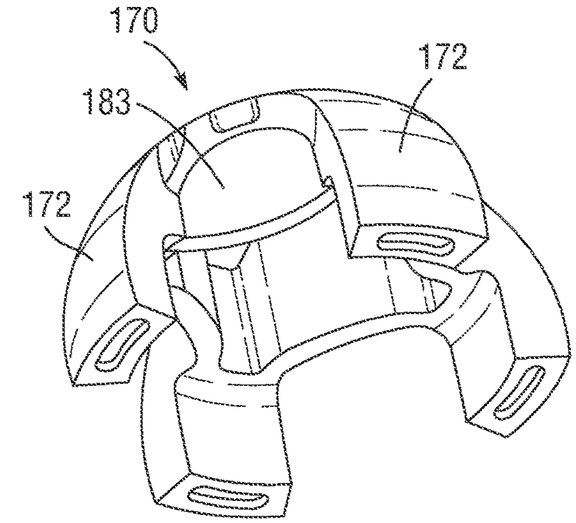

FIG. 31

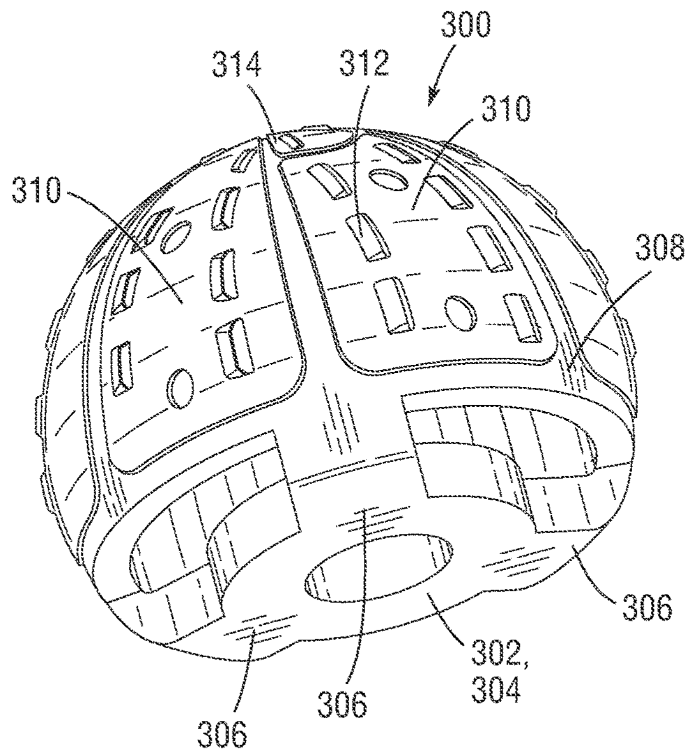

FIG. 32

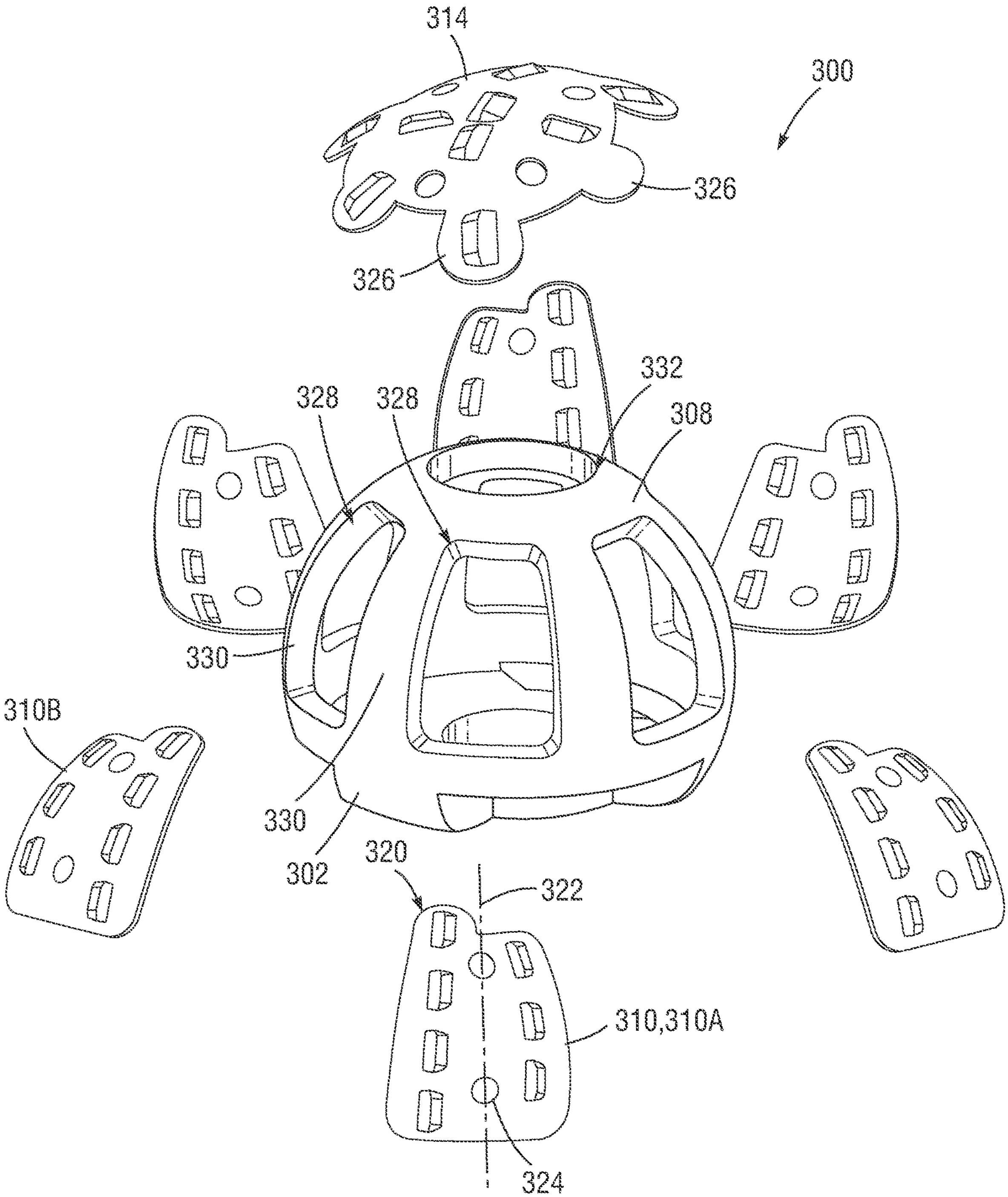
314
300
326
326
332
328
328
308
330
310B
330
302
320
322
310,310A
324

FIG. 33

SURGICAL CUTTING TOOL

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of International Patent Application No. PCT/US2021/054429, filed on Oct. 11, 2021, which application claims the benefit of U.S. Provisional Application No. 63/093,717, filed on Oct. 19, 2020. Each of the above-referenced applications is incorporated herein by reference in its entirety.

FIELD

This disclosure pertains to surgical cutting tool systems and associated methods relating to orthopedic surgery, and more specifically, preparation of prosthetic hip implantations.

BACKGROUND

Cutting tools, such as medical reamers used by surgeons, generally have a cutting surface that is able to cut and/or remove material from an object. For example, in many different disciplines in orthopedics cutting tools are used for machining bone in the preparation of artificial joints including hips, knees, elbows and shoulders, and also in the repair of long bone fractures. For example, spherical or hemispherical reamers can be used to shape the acetabulum in total hip replacement procedures. The design and method of manufacturing cutting surfaces of such cutting tools can affect the efficiency, functional life of the spherical reamer and cost in manufacturing. Accordingly, there exists a need for improvements relating to design and manufacturing of surgical cutting tools.

SUMMARY

Disclosed herein are exemplary embodiments of devices, systems, and related methods for performing orthopedic surgery. In some implementations, the devices and systems can be used in preparing a prosthetic hip implantation. In some embodiments, the devices and systems can be included in a sterile kit. In some embodiments, some of the devices can be disposable.

In some embodiments, improved cutting tools and methods of manufacturing the same are provided.

In certain implementations, the cutting tools can comprise medical reamers, including hemispherical or acetabular reamers, along with the design of different cutting teeth in specific zones of the reamers and the improved method of making these reamers and their cutting edges.

In a representative embodiment, a hemispherical cutting tool comprises a frame having a first end portion and a second end portion, and defining an axis of rotation of the hemispherical cutting tool. The cutting tool further comprises a plurality of curved side panels coupled to the frame and arranged about the axis of rotation of the cutting tool, the curved side panels comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly into the frame from edge portions of the curved side panels in a direction toward a hollow interior of the hemispherical cutting tool. The frame further comprises a dome panel coupled to the second end portion of the frame such that the cutting tool has a hemispherical shape, the dome panel comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly from edge portions of the dome panel into the frame in a direction toward the hollow interior of the hemispherical cutting tool. The frame is injection molded around the curved side panels and the dome panel such that the engagement members of the curved side panels and the dome panel are embedded in the injection molded frame.

In any or all of the disclosed embodiments, side edge portions and distal edge portions of the curved side panels comprise engagement members.

In any or all of the disclosed embodiments, the engagement members of the curved side panels comprise T-shaped members.

In any or all of the disclosed embodiments, the frame comprises a first polymeric frame member comprising an annular body, and a second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member.

In any or all of the disclosed embodiments, one of the first or second polymeric frame members comprises a plurality of coupling portions configured to be received in openings defined in the other of the first or second polymeric frame members.

In any or all of the disclosed embodiments, the cutting teeth of the curved side panels are arranged in columns, and cutting edges of the cutting teeth are longitudinally offset from each other in adjacent columns and at least partially overlap with each other in the circumferential direction.

In any or all of the disclosed embodiments, the cutting teeth of the curved side panels are arranged in columns, the cutting teeth of a central column of cutting teeth of each curved side panel are aligned with a central axis of the curved side panel, and cutting teeth of columns of cutting teeth that are circumferentially offset from the central column of cutting teeth are angled toward the central column of cutting teeth.

In any or all of the disclosed embodiments, the cutting teeth of the curved side panels comprise a long dimension and a short dimension, and the long dimensions of the cutting teeth are oriented longitudinally on a hemispherical surface of the cutting tool.

In any or all of the disclosed embodiments, the axis of rotation of the hemispherical cutting tool intersects a cutting tooth of the plurality of cutting teeth of the dome panel.

In any or all of the disclosed embodiments, the dome panel comprises a plurality of lobes separated by concave edge portions, each of the lobes comprising an engagement member.

In another representative embodiment, a hemispherical cutting tool comprises a polymeric frame comprising a first polymeric frame member coupled to a second polymeric frame member and defining an axis of rotation of the hemispherical cutting tool, the first polymeric frame member comprising an annular body and defining a first end portion of the frame, the second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member and converging toward a second end portion of the polymeric frame. A metal dome panel is coupled to the second polymeric frame member at the second end portion of the polymeric frame, the metal dome panel comprising a plurality of cutting teeth, and a plurality of curved metal side panels are coupled to the polymeric frame and arranged about the axis of rotation of the hemispherical cutting tool.

In any or all of the disclosed embodiments, the curved metal side panels comprise a plurality of engagement members extending inwardly from edge portions of the curved metal side panels into the second polymeric frame member in a direction toward a hollow interior of the hemispherical cutting tool.

In any or all of the disclosed embodiments, side edge portions and distal edge portions of the curved metal side panels comprise engagement members.

In any or all of the disclosed embodiments, the metal dome panel comprises a plurality of engagement members extending from edge portions of the metal dome panel inwardly into the second polymeric frame member in a direction toward the hollow interior of the hemispherical cutting tool.

In any or all of the disclosed embodiments, the engagement members of the curved metal side panels comprise T-shaped members.

In any or all of the disclosed embodiments, the frame is injection molded around the curved metal side panels and the metal dome panel such that the engagement members of the curved metal side panels and the metal dome panel are embedded in the injection molded frame.

In any or all of the disclosed embodiments, one of the first or second polymeric frame members comprises a plurality of coupling portions configured to be received in openings defined in the other of the first or second polymeric frame members.

In any or all of the disclosed embodiments, the cutting teeth of the curved metal side panels comprise a long dimension and a short dimension, and the long dimensions of the cutting teeth are oriented longitudinally on a hemispherical surface of the cutting tool.

In any or all of the disclosed embodiments, the axis of rotation of the hemispherical cutting tool intersects a cutting tooth of the plurality of cutting teeth of the metal dome panel.

In any or all of the disclosed embodiments, the metal dome panel comprises a plurality of lobes separated by concave edge portions, each of the lobes comprising an engagement member.

In another representative embodiment, a hemispherical cutting tool comprises a frame comprising a first polymeric frame member coupled to a second polymeric frame member and defining an axis of rotation of the hemispherical cutting tool, the first polymeric frame member comprising an annular body and defining a first end portion of the frame, the second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member and converging toward a second end portion of the polymeric frame. A plurality of curved side panels is coupled to the frame and arranged about the axis of rotation of the cutting tool, the curved side panels comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly into the frame from edge portions of the curved side panels in a direction toward a hollow interior of the hemispherical cutting tool. A dome panel is coupled to the second end portion of the frame such that the cutting tool has a hemispherical shape, the dome panel comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly from edge portions of the dome panel into the frame in a direction toward the hollow interior of the hemispherical cutting tool, and the second polymeric frame member is injection molded around the curved side panels and the dome panel such that the engagement members of the curved side panels and the dome panel are embedded in the second polymeric frame member.

In another representative embodiment, a method of making the hemispherical cutting tool of any of the embodiments described herein comprises situating the dome panel and the plurality of side panels in a mold, and injecting a polymeric material into the mold to form at least a portion of the frame.

In another representative embodiment, a method comprises cutting bone with the hemispherical cutting tool of any of the embodiments described herein.

In another representative embodiment, a cutting tool is provided with a cutting surface on a first side of the cutting tool and an attachment member on a second side of the cutting tool. The cutting surface can include a plurality of cutting edges and the attachment member can be configured to be coupled to a powered driving member (e.g., a drill). The cutting tool can comprise an axis of rotation and the cutting surface can define a plurality of latitude lines. The plurality of cutting edges can be oriented at varying orientation angles relative to the latitude lines.

In any or all of the disclosed embodiments, the plurality of cutting edges can be increased to three or more different zones and respective cutting edges in the different zones have different characteristics. The different zones can comprise a polar zone, a transition zone, and an equatorial zone. Respective cutting edges can define a cutting angle between the cutting edge and a first side of the cutting tool, and the cutting angle between cutting edges in the polar zone can be larger than those defined by cutting edges in the transition zone, and the cutting angle between cutting edges in the transition zone can be larger than those defined by cutting edges in the equatorial zone. In some implementations, the tooth height can be the same (i.e., substantially the same) regardless of the cutting angle.

In any or all of the disclosed embodiments, the orientation angles can vary depending on whether the respective cutting edges are in the polar zone, the transition zone, or the equatorial zone, and the orientation angle of respective cutting edges in the equatorial zone is greater than the orientation angle of respective cutting edges in the transition zone, and the orientation angle of respective cutting edges in the transition zone is greater than the orientation angle of respective cutting edges in the polar zone.

In any or all of the disclosed embodiments, the thickness of the side wall can be less than 0.040 inches, or in some cases, between 0.022 inches and 0.040 inches. Openings can be provided adjacent respective cutting edges, the respective openings defining a funnel angle that is between 20 and 40 degrees. In some cases, the funnel angle can be between 25 and 35 degrees.

In any or all of the disclosed embodiments, the cutting surface can be a panel and the cutting tool can comprise a plurality of separate panels. The cutting tool can include a frame member and the plurality of separate panels can be coupled to the frame member.

In another representative embodiments, a method for forming a cutting tool is provided. The method can include forming a plurality of panels from one or more flat sheets of metal and coupling the plurality of panels to a frame member to form the cutting tool. The plurality of panels can be formed with a plurality of cutting edges and a plurality of openings adjacent respective cutting edges. When coupled to the frame member, the plurality of panels can define a plurality of latitude lines about the axis of rotation of the cutting tool and the plurality of formed cutting edges have orientation angles relative to the latitude lines that vary. In some cases, respective panels can have cutting edges with orientation angles that vary along the respective panel.

In any or all of the disclosed embodiments, the act of forming a plurality of panels can comprise stamping the one or more flat sheets of metal to form a plurality of cavities and punching holes at or adjacent to the plurality of cavity to provide bone-chip-receiving openings. The act of forming the plurality of cavities can include forming a plurality of "V"-shaped cavities.

In any or all of the disclosed embodiments, the act of forming the plurality of panels can include stamping the one or more panels to create a desired height of the cutting edges and to provide a desired curvature of the one or more panels.

In any or all of the disclosed embodiments, the act of coupling the plurality of panels to the frame member can include forming a frame member that comprises a base, and a form dome, and securing the plurality of panels to the frame member and the form dome. In some cases, the act of securing the plurality of panels to the frame member and the form dome can be performed by laser welding or other types of welding. The act of coupling the plurality of panels to the frame member can also include placing the plurality of panels into an injection molding tool and injection molding the frame member around the plurality of panels to create the frame member.

In any or all of the disclosed embodiments, the act of forming a plurality of panels from one or more flat sheets of metal can include forming the plurality of cutting edges with different zones that have cutting edges with different characteristics, the different zones comprising a polar zone, a transition zone, and an equatorial zone. Respective cutting edges can define a cutting angle between the cutting edge and a first side of the cutting tool, and the cutting angle between cutting edges in the polar zone can be larger than those defined by cutting edges in the transition zone, and the cutting angle between cutting edges in the transition zone can be larger than those defined by cutting edges in the equatorial zone.

In any or all of the disclosed embodiments, the act of punching holes at or adjacent to the plurality of cavity can comprise forming bone-chip-receiving openings with a funnel angle that is between 20 and 40 degrees. In addition, in some cases, the one or more flat sheets of metal can have a thickness less than 0.040 inches (1.02 mm).

In any or all of the disclosed embodiments, the method can include determining an effective functional life of the cutting tool.

In another representative embodiment, a cutting tool is provided that can have a cutting surface on a first side of the cutting tool, the cutting surface comprising a plurality of cutting edges, and an attachment member on a second side of the cutting tool, the attachment member being configured to be coupled to a powered driving member. A plurality of cutting edges can be provided in different zones and respective cutting edges in the different zones can have different characteristics.

The foregoing and other objects, features, and advantages of the disclosed technology will become more apparent from the following detailed description, which proceeds with reference to the accompanying figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates an acetabular reamer, and the use of the reamer to prepare the acetabulum, for example axial force applied by a surgeon by pushing the cutter into the acetabulum and a second torsional force exerted by the power reaming tool as part of a total hip procedure, according to one embodiment.

FIG. **2**A illustrates an acetabular reamer with a hollow spherical cutter. FIG. **2**B illustrates use of the reamer to prepare the acetabulum. FIG. **2**C illustrates the acetabular implant in position as part of a total hip procedure.

FIG. **3**A illustrates a cutting tool composed of a sharp tooth edge, a specific tooth elevation, specific cutting angle, a specific tooth orientation to the axis of rotation and a peripheral opening around the cutting edge providing an improved flow path for the bone debris. FIG. **3**B illustrates a bone chip opening. FIG. **3**C illustrates a funnel angle for bone debris and a radial cutting edge that matches the spherical reamer.

FIG. **4**A illustrates a manufacture of cutting teeth geometry by forming a sheet. FIG. **4**B illustrates cutting tooth geometry of the sheet. FIG. **4**C illustrates a cutting tooth height set.

FIG. **5**A illustrates a cutting tool having a plurality of teeth, with one row of teeth shown for clarity. FIG. **5**B illustrates the cutting edge orientation to latitude lines and an axis of rotation of the cutting tool.

FIG. **6** illustrates a cutting tool having a plurality of teeth.

FIG. **7**A illustrates an acetabulum undersized to a reamer. FIG. **7**B illustrates a schematic view of cutting teeth zones. FIG. **7**C illustrates a primarily side cutting reaming action. FIG. **7**D illustrates a transition from side cutting to end cutting. FIG. **7**E illustrate a primarily end cutting action.

FIG. **8**A illustrates a schematic view of cutting teeth zones and their general functions. FIG. **8**B illustrates the cutting teeth of the equatorial zone. FIG. **8**C illustrates the cutting teeth of the transitional zone. FIG. **8**D illustrates the cutting teeth of the polar zone.

FIG. **9** illustrates a schematic view of cutting forces applied by a cutting tool.

FIG. **10**A illustrates frictional forces associated with bone chips created by a cutting tool with a first thickness. FIG. **10**B illustrates frictional forces associated with bone chips created by a cutting tool with a second thickness.

FIG. **11**A illustrates stamped cutting panels of a spherical reamer. FIG. **11**B illustrates an injection molding tool for creating plastic framing. FIG. **11**C illustrates a finished reamer.

FIG. **12** illustrates another embodiment of a spherical reamer.

FIG. **13** illustrates the results of an exemplary test procedure.

FIG. **14** illustrates the results of an exemplary test procedure.

FIGS. **15**A-**15**D are side, top, bottom plan views, and a perspective view, respectively, of a hemispherical cutting tool, according to another embodiment.

FIG. **15**E is an exploded view of the hemispherical cutting tool of FIGS. **15**A-**15**D.

FIGS. **16**A and **16**B are top and bottom plan views, respectively, of a curved side panel blank.

FIGS. **16**C and **16**D are magnified top and bottom plan views, respectively, of a cutting tooth of the curved side panel blank of FIGS. **16**A and **16**B.

FIG. **16**E is a cross-sectional view of a cutting tooth taken along line **16**E-**16**E of FIG. **16**B.

FIGS. **17** and **18** are perspective views of a curved side panel, according to one embodiment.

FIG. **19** is a cross-sectional view of a curved side panel taken along line **19**-**19** of FIG. **18**.

FIGS. **20**A and **20**B are top and bottom plan views, respectively, of a top panel blank, according to one embodiment.

FIGS. **21**A-**21**C are perspective, top plan, and side elevation views, respectively, of a dome panel, according to one embodiment.

FIG. **22**A is a magnified view of a representative cutting tooth of the dome panel of FIGS. **21**A-**21**C.

FIG. **22**B is a cross-sectional view of the cutting tooth taken along line **22**B-**22**B of FIG. **22**A.

FIG. **23** is an exploded view of a frame member of the hemispherical reamer of FIG. **15**A, according to one embodiment.

FIGS. **24**A and **24**B are top and bottom plan views, respectively, of a first frame member of the frame member of FIG. **23**.

FIG. **25** is a cross-sectional view of a portion of the first frame member illustrating a coupling portion.

FIGS. **26** and **27** are a perspective view and a top plan view, respectively, of a second frame member of the frame member of FIG. **23**, according to one embodiment.

FIG. **28** is a cross-sectional view of the second frame member taken along line **28**-**28** of FIG. **27**.

FIG. **29** is a perspective view of a molding apparatus for producing a frame of a hemispherical cutting tool, according to one embodiment.

FIG. **30** is a perspective of an arrangement of panels for a hemispherical cutting tool, according to another embodiment.

FIG. **31** is a perspective view of a portion of a frame to which the panels in FIG. **30** can be coupled.

FIG. **32** is a perspective view of a hemispherical cutting tool, according to another embodiment.

FIG. **33** is an exploded view of the hemispherical cutting tool of FIG. **32**.

DETAILED DESCRIPTION

General Considerations

The following description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the present disclosure in any way. Various changes to the described embodiments may be made in the function and arrangement of the elements described herein without departing from the scope of the disclosure.

Although the operations of some of the disclosed embodiments are described in a particular, sequential order for convenient presentation, it should be understood that this manner of description encompasses rearrangement, unless a particular ordering is required by specific language set forth herein. For example, operations described sequentially may in some cases be rearranged or performed concurrently. Moreover, for the sake of simplicity, the attached figures may not show the various ways in which the disclosed methods can be used in conjunction with other methods. Additionally, the description sometimes uses terms like "provide" or "achieve" to describe the disclosed methods. These terms are high-level abstractions of the actual operations that are performed. The actual operations that correspond to these terms may vary depending on the particular implementation and are readily discernible by one of ordinary skill in the art when viewed in light of this disclosure.

It should be understood that the disclosed embodiments can be adapted to prepare orthopedic surgery other than hip implantation. For example, the disclosed systems and methods can be adapted for preparation of prosthetic shoulder implantation or other surgical procedures.

As used herein, the term "proximal" refers to a position, direction, or portion of a device that is closer to the user and further away from the implantation/surgical site. As used herein, the term "distal" refers to a position, direction, or portion of a device that is further away from the user and closer to the implantation/surgical site. Thus, for example, proximal motion of a device is motion of the device away from the implantation/surgical site and toward the user (e.g., out of the patient's body), while distal motion of the device is motion of the device away from the user and toward the implantation/surgical site (e.g., into the patient's body). The terms "longitudinal" and "axial" refer to an axis extending in the proximal and distal directions, unless otherwise expressly defined.

As used herein, the term "approximately" and "about" means the listed value and any value that is within 10% of the listed value. For example, "about 10 mm" means any value between 9-11 mm, inclusive.

As used in this application and in the claims, the terms "a," "an," and "the" include both the singular and plural forms of the element(s) they refer to unless the context clearly dictates otherwise. Additionally, the term "includes" means "comprises." Further, the term "coupled" generally means electrically, electromagnetically, and/or physically (e.g., mechanically or chemically) coupled or linked and does not exclude the presence of intermediate elements between the coupled or associated items absent specific contrary language.

As used herein, the term "effective functional life" means the amount of use a tool can experience before it begins to operate sub-optimally for its intended purpose. In some embodiments, the effective functional life can be based on a number of uses of the tool and/or an amount of time the tool has been used. As used herein, the term "powered driving member" means any device capable of driving a cutting tool such as, for example, a drill.

As used herein, the term "single use" tool or instrument means a tool or instrument that is configured and/or intended to be used once before being discarded. Thus, a single use tool or instrument can be a non-reusable device in contrast to reusable tools or instruments which, subject to certain procedures such as cleaning and sterilization, may be used more than once. As used herein, the term "disposable" device or instrument means a device or instrument that is configured and/or intended to be used one or a few times before being discarded.

As used herein, the term "spherical reamer" is used interchangeably with the term "hemispherical reamer" unless the context clearly indicates otherwise.

Directions and other relative references may be used herein to facilitate discussion of the drawings and principles described herein. For example, certain terms may be used such as "up," "down,", "left," "right," "horizontal," "vertical," and the like. Such terms are used, where applicable, to provide some clarity of description when dealing with relative relationships, particularly with respect to the illustrated embodiments. Such terms are not, however, intended to imply absolute relationships, positions, and/or orientations. As used herein, "and/or" means "and" or "or", as well as "and" and "or".

Cutting Tools

It is generally desirable that cutting surfaces on a cutting tool (e.g., cutting teeth) be as accurate and consistent as possible for the dimensional accuracy of the final preparation in the bone. For example, cementless acetabular implants (press fit) are dependent on their dimension and the dimension of the bone preparation to create a reproducible interference fit for establishing initial stability of the implant. FIG. **1** illustrates an acetabular reamer and use of the reamer to prepare the acetabulum, including axial force applied by the surgeon and torsional force applied by the power tool.

The initial stability of the implant is critical to long term success and if the implant moves large amounts (e.g., 75 microns or more) under physiological loads post-operatively, it can result in soft tissue growing into the implant rather than bone. If this occurs, the implant will eventually loosen. Accordingly, the accuracy of the initial fit must provide stability of the implant to allow bone to grow into the implant during the first 6-12 weeks after surgery. In some instances, the interference level required for cementless acetabular implants can be required to be very small (e.g., less than 2 mm, and, in some cases, preferably less than 1 mm). However, commercial cutters can vary in their accuracy by as much as 0.25 mm and these variations can result in initial acetabular implant stability. Because the initial interference fit provides stability to the implant, improved accuracy of the teeth height and performance can assist in achieving this goal.

Configuration of Cutting Members

Conventional reamer designs use the same cutting tooth geometry within each design. These teeth are also positioned at 90° to the latitude lines of the spherical reamer surface. However, cutting teeth around the equator of the reamer perform a side cutting function while teeth towards the dome of the cutter perform an end cutting function.

As described in more detail herein, various embodiments are provided in which reamers utilize different cutting teeth configurations and different orientations to address the different bone cutting requirements and thereby improving the efficiency of the cut. By efficiently designing cutting teeth for specific operations, faster bone cuts can be achieved, thereby producing less friction. Minimizing the friction generated by the reamers relates directly to maintaining the life of the bone. Friction can lead to heat and if the cutter-bone interface reaches temperatures above 50° C. (122° F.) bone death (necrosis) can occur. This can affect long term success of the procedure whether the implant is used with or without bone cement. If the bone preparation bed is damaged due to excessive heat generated from the acetabular cutter, the fixation of the implant will be compromised and can lead to loosening and revision.

There are two primary forces applied to the reamer during the machining of the bone. When considering an acetabular reamer, as shown in FIGS. **1** and **2**A-**2**C, there is an axial force applied by the surgeon who pushes the cutter into the acetabulum and a second torsional force exerted by the power reaming tool. In some embodiments, the cutting tools disclosed herein convert the torsional force into a force applied at the cutting tooth edge to improve the efficiency of the cut. FIG. **2**A illustrates an acetabular reamer with a hollow spherical cutter. FIG. **2**B illustrates use of an acetabular reamer to prepare the acetabulum, and FIG. **2**C illustrates an acetabular implant press fit in the prepared acetabulum as part of a total hip replacement procedure.

The systems and methods described herein for forming cutting tools can provide greater control and accuracy of the tooth sharpness, cutting angles, and resulting bone chip removal by the tool. In addition, as described in more detail below, the cutting tools described herein can be formed by manufacturing processes that permit the creation of multiple teeth in one operation.

In the embodiments described herein, cutting surfaces (e.g., teeth) can comprise a sharp tooth edge (tolerance 0.0005" to 0.002" (0.013 mm to 0.051 mm) tooth edge radius), a specific tooth elevation (tolerance 0.002"-0.004" (0.051 mm to 0.11 mm)), specific cutting angle, a specific tooth orientation to the axis of rotation (e.g., tool angle), and a peripheral opening around the cutting edge providing a designed flow path for the bone debris as shown in FIGS. **3**A-**3**C. This tooth geometry can also be manufactured according to FIGS. **4**A-**4**C through a series of stamping operations allowing for multiple teeth to be made at the same time. For example, as illustrated in FIG. **4**A, a flat sheet of material (e.g., metal) can be stamped so that a plurality of "V"-type cavities are punched into the sheet based on a desired cutting angle ω. Next, a plurality of holes can be punched around the "V"-type cavities (or grooves), creating a cutting edge, as shown in FIG. **4**B. If necessary, another stamping step can be performed to stamp the tooth height and curvature in operation (or multiple operations if desired). As shown in FIG. **4**C, angle β determines the tooth height and angle β in conjunction with angle α (FIG. **4**A) will determine the rake angle ω ($\omega=\alpha-\beta$) of the cutting surface. In some embodiments, the rake angle can vary between about 5 and 25 degrees, and in other embodiments between about 5 and 15 degrees (e.g., about 10 degrees)

Thus, in contrast to conventional devices, the tooth angle (α) can be established in the first forming operation and can be set (ω and β angles) based on the intended function. Multiple iterations of this tooth design can be provided in specific zones of the reamer surface which address the intended type of cutting required at those locations.

In some embodiments, the cutting tools disclosed herein can have teeth arranged in a spiral or helix manner on the surface of the cutter. However, the tooth designs and tooth orientations can be optimized to reduce the reaming time required to complete the preparation. As shown in FIGS. **5**A-**8**D, the cutting edges of the teeth can be oriented at different angles to the lines of latitude based on the required cutting functions at various positions on the surface of the reamer. This can provide for a faster cut by converting the rotational energy into linear energy assisting in advancing the reamer into the preparation analogous to a screw thread (FIGS. **5**A-**5**B). FIG. **5**A shows the orientation of teeth of one row of teeth relative to latitude lines for clarity. FIG. **5**B shows the cutting edge orientation of a single tooth to latitude lines and the axis of rotation of the cutting tool. The tooth orientation can further improve the cutting force at the tooth edge. By changing the orientation of the cutting edge relative to the latitude lines, a portion of the torsional force is converted into a cutting force at the tooth edge as shown in FIG. **6**. This improvement primarily benefits the teeth closest to the equator as they are performing a side cutting function. In FIG. **6**, the angle β is the orientation of the tooth, the force F applied is represented as a downward arrow, and the additional cutting force F_{cut} is given by the equation $F_{cut}=\sin(F_{Applied})$. In certain embodiments, teeth orientation to latitude lines improved cutting force at the tooth edge.

As shown in FIGS. **5**A-**6**, the angle of orientation of the cutting edge relative to axis of rotation can increase from the equatorial teeth to the polar teeth and decrease relative to the latitude lines. At least three different types of cutting teeth (e.g., orientation angles and/or cutting angles varying) can be provided on the tool. In some embodiments, at least three regions are provided with similar type teeth in each region. In other embodiments, the teeth can vary in a transitional manner effectively providing more than three zones.

In some embodiments, relative to the latitude lines, the range of variation can be orientation angles of between 10 and 30 degrees (more preferably between 15 and 25 degrees—e.g., 20 degrees) for the equatorial zone, orientation angles of less than 5 degrees (more preferably about 0 degrees) in the polar zone, and somewhere in between for the orientation angles in the transition zone (e.g., between 0 and 20 degrees, or preferably between 5 and 15 degrees—

e.g., 10 degrees). A benefit of the larger orientation angles in the equatorial zone is a portion of the axial load applied by the operator will be converted into driving the cutting edge into the bone. As you move to the polar zone, the angle of the tooth on the surface has less effect as the tooth becomes perpendicular to the direction of the cut. That is, the specific tooth geometry in the polar zone needs to address an end cutting ability rather than a side cutting ability.

FIGS. **7**A-**7**E illustrate an exemplary process by which a cutting tool (e.g., a spherical reamer) transitions from engagement with the bone at one area to another area of the cutting tool. As used herein, the term "polar teeth" refer to cutting surfaces at and/or adjacent the pole of the spherical reamer, the term "equatorial teeth" refer to cutting surfaces at and/or adjacent to the equator of reamers having a hemispherical shape (e.g., the area furthest from the poles in FIGS. **7**A-**7**E), and the term "transition teeth" refer to cutting surfaces between the polar and equatorial teeth.

In the exemplary reaming process illustrated in FIGS. **7**A-**7**E, the spherical reamer begins by introduction into the concave surface of the acetabulum (FIG. **7**C). It is noted that this initiation of the cut involves just the equatorial teeth. These equatorial teeth are performing more of a side cutting function and therefore can have a specific tooth angle based on this intended function. Additional teeth (i.e., the transitional teeth) become engaged with the bone as the reamer is further introduced into the acetabulum. For example, in FIG. **7**D the reamer is introduced approximately 50% and the teeth are transitioning from side cutting to end cutting. The transitional teeth perform a combination of side-cutting and end-cutting and can be optimized for this purpose. As the reamer becomes fully inserted into the preparation site (FIG. **7**E), the teeth at the pole (i.e., the polar teeth) of the reamer serve to primarily end-cut.

Thus, the teeth can have different cutting demands depending on their location on the surface of the reamer and can be configured accordingly. FIGS. **8**A-**8**D illustrate the manner in which the cutting angles of the teeth can vary in accordance with the required cutting function of the bone. The table below illustrates the types of teeth and their configurations as reflected in FIGS. **8**A-**8**D.

edge radius, funnel angle, or tooth height, whereas the teeth in two adjacent zones can have different tooth edge radius, funnel angle, or tooth height.

In alternative embodiments, the teeth in each of the three zones can vary in characteristics (cutting angles, tooth edge radius, funnel angle, tooth height, etc.). For example, the cutting surfaces can transition gradually from one zone to another. Thus, polar teeth can transition gradually from polar teeth with the orientation and characteristics noted above to transition teeth with the orientation and characteristics noted above. In this manner, for example, some teeth can have orientation and characteristics of polar teeth (e.g., 65 degree cutting angle), some can have characteristics of transition teeth (e.g., 45 degree cutting angle), and some teeth between the polar teeth and transition teeth can have characteristics somewhere inbetween (e.g., 55 degree cutting angle). In one example, the cutting angle in the polar zone may gradually decrease from about 70 degrees at the pole region to about 60 degrees at the polar-transition zone boundary; the cutting angle in the transition zone may gradually decrease from about 50 degrees at the polar-transition zone boundary to about 40 degrees at the transition-equatorial zone boundary; and the cutting angle in the equatorial zone can gradually decrease from about 30 degrees at the transition-equatorial zone boundary to about 20 degrees at the equatorial region.

Proper bone chip exit paths can also contribute to an improved surgical preparation. With a non-impeded path for the bone chips to travel away from the cutter, it enables the instrument to produce a faster and cooler bone cut. As shown in FIGS. **3**A-**3**C, openings can be provided adjacent cutting surfaces to provide a "funnel" that permits bone chips to efficiently flow from the face of the reamer to avoid additional torque requirements to drive the cutter. Without such openings, increased torque is required to drive the cutting tool and such increased torque is usually accompanied by increased axial pressure as the operator senses the resistance in advancing the cutter and applies increased loads. This combination generates increased heat through friction capable of generating temperatures which can cause bone necrosis.

Manufacturing of Cutting Tools

Teeth Region	Cutting angle (defined relative to a side surface of the cutting tool)	Tooth edge radius	Funnel angle	Tooth height
Equatorial	15-35 degrees (more preferably, 20-30 degrees)	0.0005-0.002" (0.013 mm-0.051 mm)	20-40 degrees, (more preferably, 25-35 degrees)	0.020" (0.51 mm) ± 0.002" (0.051 mm)
Transition	35-55 degrees (more preferably, 40-50 degrees)	0.0005-0.002" (0.013 mm-0.051 mm)	20-40 degrees, (more preferably, 25-35 degrees)	0.020" (0.51 mm) ± 0.002" (0.051 mm)
Polar	55-75 degrees (more preferably, 60-70 degrees)	0.0005-0.002" (0.013 mm-0.051 mm)	20-40 degrees, (more preferably, 25-35 degrees)	0.020" (0.51 mm) ± 0.002" (0.051 mm)

In certain embodiments, the teeth in each of the three zones can generally have the same characteristics, whereas the teeth in two adjacent zones can have different characteristics. For example, the teeth in each zone can have the same cutting angle, whereas the teeth in two adjacent zones can have different cutting angles. In one exemplary embodiment, the teeth in the equatorial zone can have the same first cutting angle (e.g., 25 degrees), the teeth in the transition zone can have the same second cutting angle (e.g., 45 degrees), and the teeth in the polar zone can have the same third cutting angle (e.g., 65 degrees). Similarly, the teeth in each of the three zones can generally have the same tooth

In some embodiments, the cutting tools can be manufactured by forming the spherical body and teeth from thinner sheet metal, 0.005"-0.020" (0.127 mm to 0.51 mm), which can improve the efficiency in manufacturing (longer tool life of the forming tools) and ability to create a sharp tooth edge without a specific sharpening operation. In addition the thinner material better dissipates the heat generated from the friction of cutting the bone over a thicker walled, heavier mass reamer. The thinner material also produces less friction, therefore a lower temperature at the surface (friction heating), through reduction of the Coriolis forces (FIG. **9**). With reference to FIG. **9**, the Coriolis force can be given by the equation $F_c=-2m\Omega(v)$, where m is the mass of the reamer, Ω is the angular velocity vector, and v is the velocity of the rotating system.

FIGS. **10**A and **10**B illustrate a comparison of the frictional forces associated with bone chips created by cutting tools having different thicknesses. As shown in FIG. **10**B, for thicker walled cutters (e.g., cutters with wall thicknesses greater than 0.022" (0.56 mm)), the bone chip particles must travel a greater distance in contact with the cutting surface of the cutter. As a result, lower temperatures can be achieved by producing cutters with wall thickness of between 0.005" and 0.020" (0.127 mm and 0.51 mm). As shown in FIGS. **10**A and **10**B, a cutter with a wall thickness of 0.56 mm to 1 mm can result in a particle travel distance four times greater than the particle travel distance of a cutter with a wall thickness of 0.127 mm and 0.51 mm. The following manufacturing methods can be used to produce cutting tools with such reduced wall thicknesses.

Using the manufacturing techniques described herein, any number of teeth (e.g., 1-20 or more) can be made in a single forming step. In contrast, conventional systems require multiple forming steps for each individual tooth. Because the number of operations required to manufacture a spherical reamer can be greatly reduced, the costs are similarly reduced, thereby providing a lower cost, yet equally effective, cutting tool that can be removed from clinical service at a the end of its functional life without significant financial loss.

It should be understood that the supporting structure for the panels can be formed in various manners. For example, FIGS. **11**A-**11**C illustrate an alternative approach in which the panels are secured by a plastic molded part. FIG. **11**A illustrates the stamped cutting panels. FIG. **11**B illustrates a representative plastic frame that can be injection molded around the stamped metal panels of FIG. **11**A. FIG. **11**C illustrates a finished reamer formed by this process that is structurally sound through the frame and maintains cutter sphericity and tolerances with 0.004 inch (0.1 mm)

In some embodiments, the panels are placed directly into an injection molding tool and a medical grade plastic (e.g., PEI (polyetherimide, ULTEM®), PEEK (polyetheretherketone), PAI (polyamidide, TORLON®) can be injected around the periphery of the panels creating a frame that encloses and secures the panels.

The cutting tools can be color coded to facilitate identification of the various sizes and types of cutting tools. When the cutting tool frames are formed by injection molding, such color coding can be achieved by varying the color of the injection molded plastic part.

Laboratory testing of a disclosed embodiment provided a comparison to existing art spherical reamers. Bovine bone specimens were used to monitor the speed to prepare a standard preparation, the temperature generated during that preparation and how many preparations could be completed before cutting edge damage generated a temperature exposure to the bone above 50° C. (122° F.). FIG. **13** summarizes the results of this testing and illustrates some of the improvements, such as the ability to cut bone at a lower temperature for a greater number of uses.

All cutting tools will eventually wear at the cutting edges resulting in a non-efficient cutter which would need to be sharpened or discarded. This is true of all industries including the medical field where these cutters are machining bone. In this field, the consequences of the cutter becoming dull and continuing to use it can result in bone necrosis. This in turn can jeopardize the success of the surgical procedure as the prosthesis must be supported by live, healthy bone to stabilize the implant. Excessive heat will kill the bone leading to bone resorption and a less than ideal interference fit between the bone and the implant. The rounding of the teeth cutting edges and damage to these edges can be demonstrated after 4-6 uses of these reamers in cow bone. It is for that reason all cutters should be qualified through laboratory testing to define the maximum number of uses under worst-case conditions which will not violate the temperature threshold for killing bone. This test result can then be used as a method to identify when the cutter should be removed from use.

FIG. **13** illustrates the results of an exemplary test procedure in a laboratory test set-up for determining the effective functional life of a cutting tool. In these tests, acetabular reamers were used to cut bone (i.e., cortical bovine bone) to determine the number of uses the acetabular reamers can experience before the end of their effective functional life. In one example, it was determined that approximately six (6) uses of the reamer produces a complete preparation without generating excessive heat (e.g., temperatures at or above 122° F. (50° C.)).

FIGS. **13**-**14** also illustrate the results of an acetabular reamer evaluation in bovine bone, including (1) a chart showing the functional evaluation of a 50 mm acetabular reamer to cut bovine bone, graphing the number of bone preparations (i.e., uses of the cutting tool) and the temperature in the bone preparation area (FIG. **13**); and (2) a chart showing the functional evaluation of a 50 mm acetabular reamer to cut bovine bone, graphing the number of bone preparations (i.e., uses of the cutting tool) and the time required to achieve the bone preparation (FIG. **14**). As shown in FIG. **13**, continuing to use the cutter after the sixth use consistently resulted in a longer preparation time and increased heat generation. The sharpness of the teeth cutting edges are directly proportional to the load required to advance the cutter, and therefore the resulting friction/heat generated. As the cutting edge rounds (or dulls), it becomes less effective in penetrating the surface of the bone and requires additional load to attempt to advance it. This cutter wear is generally consistent for all cutting tools.

FIG. **12** illustrates another exemplary cutting tool configured as a hemispherical reamer. The cutting tools and methods of manufacturing the same can provide a number of improvements, including (in certain embodiments) at least some of the following improvements:

1. Multiple teeth designs and teeth orientations to address multiple machining needs of the bone yielding a faster, cooler cut.
2. Tooth design geometries which address side cutting, end cutting and a combination of both.
3. A thinner material for forming the spherical reamer which can improve sharpness and reduction of heat.
4. A thinner material which also provides for more efficient forming of teeth and component parts improving manufacturing tool life.
5. Ability to produce multiple teeth designs and multiple teeth in fewer manufacturing steps.
6. A method of assembling a spherical reamer using multiple panels, pre-stamped with teeth of specific geometry and orientation.

In certain embodiments, the approach to producing more efficient medical reamers described herein can help ensure a proper bone preparation for patients with varying anatomy and/or pathology. In addition, the cutting tools described herein can provide improved sharpness, reduced heat during the reaming and a faster preparation based on tooth geometry and orientation. These improvements are also possible through a less expensive manufacturing process which makes it more economical to discard the reamer when it becomes dull.

Functional Life of Cutting Tools

It is also desirable to understand the effective functional life of the cutting tools described herein. As with any cutting tool, no matter how efficient the cutter has been designed, it will dull after multiple uses and its effective life will have terminated. Currently medical spherical reamers are used multiple times without any monitoring of the status of where the cutter is in its life cycle. Hospitals receive a new spherical reamer and follow an instrument processing procedure that includes cleaning, sterilizing, use, cleaning, sterilizing, and reuse. However, that cycle can continue for many, many surgical procedures before a surgeon notices the reamer is not cutting well.

Cutting teeth dull after even a few uses and dull cutting teeth generating heat that can be sufficient to cause bone necrosis. Accordingly, in addition to improving teeth design, it can also be helpful to provide the ability to indicate when a cutter should be removed from use to avoid issues relating to bone necrosis from dull cutters. In conventional approaches, instruments are used in hospitals on patients many times without knowledge of the life expectancy of the reamer and often beyond the functional life of the instrument. Some of the reluctance to discard the instrument after a single use is the cost of manufacturing these instruments. It is also perceived by the medical industry through orthopedic surgeons that these instruments do have a functional life greater than a single use. Accordingly, significant improvements in manufacturing costs, such as those realized by the embodiments described herein, can help to reduce the number of uses needed to obtain a return on investment.

The methods described herein can create more cost effective cutting tools, such as spherical/hemispherical reamers. In addition, the methods described herein can provide a means for defining the effective functional life of the cutting tools and providing a method of knowing when to discard it to ensure that the cutting tool used for any procedure (e.g., a total hip procedure) will be effective for its intended purpose.

In at least some of the embodiments described herein, as described above, medical reamers can include at least some of the following design parameters, enabling the production of more efficient tools for cutting bone:

1. Optimize forces applied to the reamer.
2. Thin, sharp tooth edge.
3. Specific tooth designs and tooth orientations providing a faster completion of the reaming cycle.
4. Adequate bone chip exit path to minimize friction from the flow of the chips at the cutter surface.
5. Minimize friction from cutting by using thinner materials and improved tooth geometry.
6. Define the functional life of the cutting edges through laboratory testing to know when to discard the reamer.
7. Provide an improved and efficient manufacturing process.

Laboratory testing to confirm an improved speed of the preparation, a lower cutting exposure temperature to the bone and an increased functional life to the reamer.

Additional Embodiments of Hemispherical Cutting Tools

FIGS. **15**A-**15**E illustrate another embodiment of a cutting tool configured as a spherical or hemispherical reamer **100**. The hemispherical reamer **100** can comprise a plurality of panels (e.g., stamped panels) coupled to a frame. In the illustrated embodiment, the reamer **100** can comprise a base portion, first end portion, or equatorial portion **102**, and a top end portion, second end portion, or pole end portion **104** located at the top of the hemispherical body. In the illustrated embodiment, the reamer **100** can comprise a plurality of curved first panel members referred to herein as side panel members or side panels **106** arrayed circumferentially around the reamer. The reamer **100** can further comprise at least one second panel member referred to herein as a dome panel **108** located at the top or pole of the reamer. The panels **106** and **108** can be secured to a frame **110**, which in certain embodiments can be an injection molded polymeric frame. In the illustrated configuration, the hemispherical reamer **100** includes four side panels **106** circumferentially spaced apart by 90°, although the reamer can include any number of side panels **106** at any angular spacing. The hemispherical reamer **100** can be driven about its central axis or axis of rotation **121**.

In certain embodiments, the panel members **106** and/or **108** can be metal panels stamped and/or laser cut to a specified shape. In certain embodiments, the panels can be stamped or cut from flat sheet stock, and can undergo one or more additional processing or forming steps to, for example, form cutting edges or cutting teeth, to be formed into a concavo-convex/curved shape, etc. In certain embodiments, the panel members **106/108** can comprise any of various high-strength, bio-compatible metals such as stainless steel, carbon steel, titanium or titanium alloys, tungsten carbide, nickel-titanium alloys, etc.

FIGS. **16**A-**16**E illustrate a representative embodiment of a side panel member blank **112** which can be further processed to form a side panel member **106**. FIG. **16**A illustrates a first or outer surface **123** of the blank **112** configured to be on the exterior of the reamer **100**, and FIG. **16**B illustrates a second or inner surface **125** of the blank **112** configured to be on the interior of the reamer. The blank **112** can be, for example, stamped or laser cut from flat sheet stock. The blank **112** can comprise a main body portion **114** having a first or proximal end portion **116** with a straight edge portion, and a second or distal end portion **118** with a curved edge portion. Side edge portions **120** and **122** can extend between the first end portion **116** and the second end portion **118**, and can curve inwardly generally toward a longitudinal axis **124** of the blank.

Referring to FIG. **16**A, the blank **112** can comprise a plurality of engagement members **126** extending from some or all of the edge portions. In the illustrated embodiment, the blank **112** can include engagement members **126** extending from the edge portions **120**, **122**, and **118**, although other combinations are possible. For example, in other embodiments the blank **112** can include engagement members **126** extending from each edge portion including the first edge portion **116**, or only the side edge portions **120** and/or **122**, or combinations of the first or second end portion **116**, **118** and one or both of the side edge portions **120**, **122**. In the illustrated embodiment, the engagement members **126** are T-shaped members with first members **128** coupled to the main body **114** of the blank, and second members configured as cross members **130** at the ends of the engagement members **126** and forming free ends of the engagement members. In the illustrated embodiment the blank **112** includes seven engagement members **126**, although the blank can include any number of engagement members having any shape, spacing, and/or size. In certain embodiments, the engagement members can define openings (e.g., in the members **128**) to allow material of the frame **110** to flow through the openings to interlock the panel **106** to the frame. In yet other embodiments, the engagement members **126** can be L-shaped (e.g., with a cross member **130** extending from one side of the first member **128**), or can include more than one cross member extending in different planes, such as a second cross member extending into and/or out of the plane of the page in FIG. **16**A.

The blank **112** can comprise a plurality of cutting teeth **132** arranged in one or more columns. In the illustrated embodiment, the blank **112** includes three columns **134**A, **134**B, and **134**C of cutting teeth **132**. Each of the columns includes three cutting teeth **132**, although in other embodiments the blank can include more or fewer columns and/or teeth. In the illustrated embodiment, the central column **134**B of cutting teeth is aligned with the axis **124**, while one or more of the teeth of the columns **134**A and **134**C can be angled inwardly toward the axis **124**, although the columns **134**A and **134**C can also be aligned with the axis **124**. For example, referring to the column **134**A by way of illustration, the lowermost cutting tooth **132**A of the column can be aligned or substantially aligned with the axis **124**, while the second cutting tooth **132**B can be inclined or angled toward the axis **124** by an angle θ_1 relative to a line parallel to the axis **124**, and the uppermost tooth **132**C can be angled toward the axis **124** by an angle θ_2, which in some embodiments can be greater than the angle θ_1. In certain embodiments, the angle θ_1 and/or the angle θ_2 can be from 1° to 45°, 2° to 30°, 3° to 30°, 1° to 10°, 1° to 20°, 3° to 10°, 3° to 20°, etc.

Referring to FIG. **16**C, the cutting teeth **132** can comprise openings/slots defined in the panels and having a first/major/long axial dimension L_1 oriented generally along the longitudinal axis **124** (FIG. **16**A), and a second/minor/short axial dimension L_2 extending generally along an axis perpendicular to the axis **124** in the plane of the page. In certain embodiments, once the blank **112** has been formed into a curved/concavo-convex shape and attached to the cutter, the long axial dimension L_1 can extend longitudinally along the hemispherical surface of the cutter (e.g., along lines of longitude between the equatorial portion **102** and the polar end portion **104**). With reference to the representative cutting tooth **132**D illustrated in FIG. **16**C, in the illustrated embodiment the cutting surfaces/edges **138** of the teeth are located on the left-hand aspect of the cutting teeth, and the direction of rotation or cutting direction is to the right as indicated by arrow **140**.

In the illustrated embodiment, the major axes of the cutting teeth of the respective columns can be configured such that an arc swept by one tooth overlaps with one or more other teeth in adjacent columns. For example, returning to FIG. **16**A the longitudinal position of the cutting tooth **132**A along the axis **124** at least partially overlaps with the longitudinal position of cutting tooth **132**D in column **134**B which, in turn, at least partially overlaps with the cutting tooth **132**E of column **134**C. The cutting edges of cutting teeth of adjacent or sequential columns (e.g., in the direction of rotation) are thus longitudinally offset from each other along the surface of the reamer. The cutting teeth **132**A and **132**E also partially overlap in the circumferential direction. In this manner, the various cutting teeth of the reamer sweep an area that is coextensive with the surface area of the reamer (e.g., there are few if any locations on the surface of the reamer where incident bone will not be cut by the cutting teeth). In certain embodiments, the cutting tooth configurations can lend themselves to manufacture by stamping, and can advantageously create an opening to allow bone debris to flow into the body of the reamer during cutting. For example, in certain embodiments the opening of the cutting teeth can be stamped or punched in a first step, and the edge intended to form the cutting edge (e.g., edge portion **138** in FIG. **16**C) can be upset or uplifted in a second stamping step that does not punch or extend through the panel. In certain embodiments, the cutting edge can also be simultaneously pressed/compressed during the uplifting step. This can stamp/compress/extrude the material, thereby reducing its thickness to form a sharp cutting edge. For example, in a representative embodiment the material thickness prior to the edge formation stamping step can be 0.012 inch (0.30 mm), and the resulting edge after stamping can have a thickness of 0.003 inch (0.076 mm), yielding a thin, sharp cutting edge.

In the illustrated embodiment, the blank **112** can also include one or a plurality of round openings **142** (FIG. **16**A) defined in the main body. In certain embodiments, openings **142** can function as datum holes/openings to facilitate accurate positioning of the panels in the injection molding tool when forming the frame as described below.

FIG. **16**D is a magnified view of the inner surface of the representative cutting tooth **132**A. The region **133** indicates the portion of the panel which can be uplifted during the second stamping step described above.

FIG. **16**E is a magnified cross-sectional view taken along line **16**E-**16**E in FIG. **16**B. The cutting tooth **132**D can comprise an external surface **162** and an angled internal surface **164** which can meet or coincide at an edge portion **138**. In certain embodiments, the edge portion **138** can form the cutting edge of the tooth, as discussed in greater detail with reference to FIG. **22**B below. In certain embodiments, the internal surface **164** can define an angle θ_3 (e.g., measured relative to the surface of the panel). In certain embodiments, the angle θ_3 can be 60° to 120°, 80° to 100°, or 90° in particular embodiments.

FIGS. **17**-**19** illustrate the blank **112** after it has been formed into a curved side panel **106**. In certain embodiments, the main body **114** can be formed/bent/pressed into a curved shape, and the engagement members **126** can be bent or curved such that they extend radially inward (e.g., toward the interior of the body of the hemispherical reamer and/or toward the central axis **121** of the hemispherical reamer). In certain embodiments, the engagement members **126** can be formed by stamping, and can be bent toward the interior of the reamer body in a separate stamping step, or together with one of the stamping steps above (e.g., formation of the cutting teeth).

FIGS. **20**A and **20**B illustrate a representative example of a dome panel member blank **144**, according to one embodiment. FIG. **20**A illustrates the outer surface **145** of the blank, and FIG. **20**B illustrates the inner or interior surface **147** of the blank. The dome panel blank **144** can comprise a main body portion **146** and a plurality of extension portions, apices, or lobes **148** around its perimeter. For example, in the illustrated embodiment the blank **144** includes four lobes **148**, with each lobe defining a corner of a generally rectangular or square outline of the main body portion **146**. Curved edge portions **150** can extend between the lobes **148**. The curved edge portions **150** can comprise concave or inwardly recessed/curved edges **152** at least partially defining the perimeter of the blank **144** between the lobes **148**.

The blank **144** can comprise a plurality of engagement members **154** extending outwardly from the edge portions of the blank. For example, in the illustrated embodiment each curved edge portion **150** includes two engagement members **154**, and each lobe **148** includes an engagement member axially aligned with the lobe **148**, although the blank may include more or fewer engagement members arranged in any arrangement. In the illustrated embodiment, the engagement members **154** are configured as T-shaped members similar to the engagement members **126** of FIG. **16**A, but may have different configurations.

The blank **144** can further comprise a plurality of cutting teeth **156**. In the illustrated embodiment, the blank **144** can comprise a cutting tooth **156** axially aligned with each lobe **148** (e.g., wherein an edge of the cutting tooth structure is aligned with the longitudinal axis bisecting the lobe **148**). The blank **144** can also include one or a plurality of circular openings **158** defined in the panel member, which can be configured as datum openings as described above.

FIGS. **21**A-**21**C illustrate the blank **144** after it has been formed into the dome panel **108**. The main body portion **146** can be curved or concave according to the curvature of the hemispherical reamer **100**. The engagement members **154** can be bent/folded/curved such that they extend from the main body portion **146** at an angle generally in a direction away from the apex **160** (FIG. **21**C) of the outer surface **145** on the concave side of the panel. With reference to FIG. **21**C, in certain embodiments the engagement members **154** of axially aligned lobes **148** (e.g., lobes on opposite sides of the main body portion from each other) can define an angle α. In certain embodiments, the angle α can be 1° to 30°, 1° to 20°, or 5° to 15°. In particular embodiments, the angle α can be 10°. In certain embodiments, the engagement members **154** of the dome panel **108** can be arranged such that in the assembled reamer, the engagement members **154** of the dome panel **108** are arranged alternatingly with the engagement members **126** of the curved side panels **106** at least where the curved distal end portions **118** of the side panels **106** are received by the corresponding curved edges **152** of the dome panel (FIG. **15**B).

In certain embodiments, the dome panel **108** can comprise a central or longitudinal axis **157** illustrated in FIG. **21**C, and indicated by the intersection of dashed lines **159** and **161** in FIG. **21**B. In certain embodiments, the axis **157** can be aligned with the axis **121** of the reamer after assembly. In the illustrated embodiment the dome panel **108** can comprise a first or innermost cutting tooth **156**A having a cutting edge **163** that is located on, coincident with, or intersects the longitudinal axis **157** (e.g., in FIG. **21**B the longitudinal axis **157** extends into the plane of the page tangent to the cutting edge **163**). In the illustrated embodiment, longitudinal axis **157** can divide the cutting edge **163** into a first portion **165** and a second portion **167**. The first portion **165** can be larger than the second portion **167** such that the center of the cutting edge **163** is offset radially outwardly from the longitudinal axis **157** toward the edge of the dome panel. Because the cutting edge **163** extends across the longitudinal axis **157**, the cutting edge sweeps around and/or across the longitudinal axis **157** when the reamer is rotated. Additionally, the path/arc swept by the cutting teeth **156**B and **156**C can at least partially overlap with the path/arc swept by the cutting tooth **156**A. In this manner, the teeth of the dome panel **108** can be staggered, overlapping, and/or configured to avoid creating a positive burr of bone at the north pole of the reamer. The paths of the cutting teeth **156**B and **156**C, in turn, can overlap with the paths of the cutting teeth **156**D, **156**E, and **156**F, and so on to the outermost cutting teeth.

FIGS. **22**A and **22**B illustrate a representative embodiment of a cutting tooth **156** (or **132**) after formation of the cutting edges **138**. As noted above with reference to FIG. **16**E, the cutting teeth can comprise a first or outer surface **162** and a second or inner surface **164** that meet at the cutting edge **138**. The surface **162** and the surface **164** can define an angle ω_1. In certain embodiments, the angle ω_1 can be 30° to 70°, 40° to 60°, or 45°. The outer surface **162** can also define an angle ω_2 with an axis **166** tangent to the cutting edge **138** at the apex of the surfaces **162** and **164**. In certain embodiments, the angle ω_2 can be 10° to 60°, 15° to 45°, 20° to 30°, or 25°. The cutting surfaces **138** can also have a tooth height H, which can be 0.25 mm to 1 mm, such as 0.5 mm, or any of the tooth heights described herein.

FIG. **23** illustrates a representative embodiment of the frame **110**. In certain embodiments, the frame **110** can comprise a first/lower/base member or portion **168**, and a second/upper/top member or portion **170**. The second frame member **170** can comprise a plurality of angularly spaced, curved extension members **172** configured to engage the first member **168**.

For example, FIGS. **24**A and **24**B illustrate top and bottom plan views, respectively, of the first member **168**. Referring to FIG. **24**A, the first member **168** can comprise an outer annular body, portion, and/or ring portion referred to hereinafter as a ring member **174**. The first member **168** can further comprise four cross members **175**, **176**, **177**, and **178** extending across the inner diameter of the ring member **174** and joined at the center of the ring member. Any or all of the ring member **174** and/or the cross members **176**-**178** can comprise a round or curved cross-section (e.g., as shown in FIG. **25**).

The upper/distal aspect or surface of the first member **168** can comprise a plurality of coupling portions generally indicated at **180** (FIG. **24**A) arranged circumferentially around the member **174**. As best shown in FIG. **24**A, in the illustrated embodiment the coupling portions **180** can be curved in the circumferential direction, although the coupling portions can also be straight. With reference to FIG. **25**, each of the coupling portions **180** can comprise a recessed portion or surface **182** offset inwardly toward the central axis of the ring member **174** (e.g., in the proximal direction when the reamer is oriented for use). The coupling portions **180** can further comprise a first extension portion or projection **184** extending outwardly from the surface **182**, and a second extension portion or projection **186** extending outwardly from the first projection **184**. In the illustrated embodiment, the cross-sectional shape of the first projection **184** can be generally rectangular, and can comprise tapered or chamfered edges. The cross-sectional shape of the second projection **186** can be triangular, although the second portion can also be rectangular, round, etc. In certain embodiments, one or both of the first projections **184** and/or the second projections **186** can be curved (FIG. **24**A), and can have a radius proportional to the radius of the equatorial portion **102** of the hemispherical reamer. In certain embodiments, one or both of the first projections **184** and/or the second projections **186** can be curved along an arc of a circle. Referring again to FIG. **25**, in certain embodiments the surfaces of the triangular projections **186** can define an angle β of, for example, 20° to 70°, 30° to 60°, 40° to 50°, or 48°.

In the illustrated embodiment, the first member **168** comprises four coupling portions **180** and corresponding projections **184** and **186**, but can include any number of coupling portions and/or projections. In other embodiments, one or more of the coupling portions **180** can comprise projections while one or more of the coupling portions comprise openings, recesses, or other coupling structures.

FIGS. **26**-**28** illustrate the second frame member **170** in greater detail. The second frame member **170** can comprise a first end portion generally indicated at **188** and a second end portion generally indicated at **190**. The second end portion **190** can comprise an annular portion or collar portion **192**. The extension members **172** can extend from the collar portion **192** and can curve outwardly relative to a central axis **194** (FIG. **23**) of the second end portion **190**. The extension members **172** can be curved in the longitudinal direction such that they converge toward the second end portion **190**. The extension members **172** can also be curved or rounded in the circumferential direction relative to the axis **194** according to the hemispherical shape of the assembled reamer such that the panel members and extension members cooperate to form the outer surface of the hemispherical reamer. Referring to FIG. **26**, the first end portion **188** can be at least partially defined by free end portions **196** of the members **172**, and can have a diameter that is greater than the diameter of the annular portion **192**.

Referring again to FIG. **26**, the free end portions **196** of the extension members **172** can comprise curved openings/recesses/channels **198** extending generally in the circumferential direction and configured to receive the coupling portions **180** (e.g., the projections **184** and/or **186**) of the first frame member **168**. In other embodiments, the first frame member **168** can comprise openings similar to the openings **198** and the second frame member **170** can comprise coupling portions including one or more extensions or projections.

Referring to FIG. **27**, the collar portion **192** can have a generally quadrilateral, rectangular, or square perimeter or outline. The collar portion **192** can comprise radiused or curved recessed portions **103** at each corner of the collar portion. Straight edge portions **105** can extend between the recessed portions **103**. In certain embodiments, the second frame member **170** can provide structural support for the spherical reamer. The second frame member **170** can have a thickness sufficient to encapsulate the T-shaped engagement members **154** of the various panels. For example, the extension members **172** can be sufficiently thick in the radial direction that the engagement members **154** of the panel members can be embedded in the extension members. The extension members **172** can also be of sufficient strength and thickness to allow assembly of the first frame member/back plate **168** onto the frame member **170**, and to resist deformation as the reamer is driven with a driver/power tool coupled to the first frame member **168**.

FIG. **28** is a cross-sectional view of the second frame member **170** taken along line **28**-**28** of FIG. **27**. In the illustrated embodiment, the second frame member **170** comprises four extension members **172**, but in other embodiments the frame member can include more or fewer extension members, such as three extension members (FIG. **32**), five extension members, six extension members, etc.

In a representative example, the various panels **106** and **108** can be stamped, cut (e.g., laser cut), milled, punched, etched (e.g., as part of a lithography process) etc., from metal sheet stock, and the various cutting teeth, openings, and/or engagement members can be formed according to any of the methods described herein. The various panels **106** and/or **108** can then be formed to the appropriate curvature. In certain embodiments, the flat panels can be curved through a series of dies which progressively bend the panels to the specified panel contour. In certain embodiments, such bending can be done in a series of steps to avoid abrupt changes in geometry, which can result in cracks in the panel material. In certain embodiments, after the panel has been formed to the specified contour/radius, the T-shaped engagement members **126**/**154** can be bent inwardly, for example, in a stamping operation.

The panels **106** and **108** can then be situated in a form/mold/fixture, and some or all of the frame member **110** can be injection molded around the panels such that at least a portion of the outer surfaces of the panels are exposed, and such that at least the engagement members **126**/**154** are embedded in the frame member **110**. For example, in certain embodiments one or both of the frame members **168** and/or **170** can be injection molded around the panels **106**, **108**. In certain embodiments, the frame member **170** can be injection molded around the panel members, and the frame member **168** can be separately formed and attached to the frame member **170** and/or to the lower edges of the side panels **106** (e.g., by heat bonding, sonic welding such as ultrasonic welding, adhesive, fasteners, or any other fastening or securing means). In certain examples, adhesive can be applied to the coupling portions **180** of the first frame member **168** and/or to the openings **198** after formation of the second frame member **170**. In certain embodiments, the male coupling portions **180** of the first frame member **168** can be mated with/received in the female openings **198** in the extension members **172** of the second frame member **170**, and the frame members **168** and **170** can be ultrasonically welded together at the junctions. In certain embodiments, the frame members **168** and **178** can both be injection molded around the panels (e.g., in the same molding operation). In certain embodiments, the frame can be a unitary body in which the first frame portion and the second frame portion are integrally formed.

In a representative embodiment, the frame member **170** can be formed in an injection molding tool, such as in a representative mold **200** illustrated in FIG. **29**. The mold **200** can comprise two separable portions or halves **202** and **204** which, when coupled together, can define a cavity shaped to produce the frame member **170**. The portion **202** can define a recess **206** comprising a plurality of smaller recesses or indentations **208** configured to accommodate the cutting teeth of the panels **106**/**108**. The portion **204** can comprise a projection/extension portion **210** comprising grooves **212** corresponding to the extension members **172** of the frame member **170**.

To produce the frame member **170**, a plurality of stamped panels **106** and **108** can be positioned within the mold (e.g., in or on the mold portion **202** and/or **204**). The portions **202** and **204** can then be assembled/secured together such that the projection portion **210** of the member **204** is received in the recess **206** of the member **202**, and material (e.g., a polymeric material/plastic material) can be injected into the cavity to create the second frame member **170** with incorporated panels **106**/**108**. The polymeric material can include any suitable injection-moldable, medical grade plastic (e.g., PEI (polyetherimide, ULTEM®), PEEK (polyetheretherketone), PAI (polyamidide, TORLON®)). The frame member **168** can be formed in a similar manner by injection molding, and can be secured to the frame member **170** with the incorporated panels as described above to create the reamer **100**.

The hemispherical reamer **100** can provide a number of significant advantages. For example, the hemispherical reamer **100** can be quickly and economically produced, and can provide the cut accuracy and low temperature/low friction operation of significantly more expensive reamers. This can allow hemispherical reamers according to the embodiments described herein to be more economically discarded at the end of their useful lives, reducing the risk of heat-related necrosis from dull cutters, the risk of surgical site infection, and the expense of cleaning and sterilizing cutters for repeated use on multiple patients.

FIGS. **30** and **31** illustrate another embodiment of the hemispherical cutting tool **100** in which the dome panel **108** has cutting teeth **179**A and **179**B (FIG. **30**) with corresponding openings that are interconnected by a slot **181** extending over the pole of the dome panel and separating the oppositely oriented cutting edges of the teeth **179**A and **179**B. Referring to FIG. **31**, the second frame member **170** can comprise walls **183** extending distally from the second end portion **190** between extension members **172**.

FIG. **32** illustrates another embodiment of a hemispherical cutting tool **300**. The hemispherical cutting tool **300** can comprise a first or distal frame member **302** (e.g., an injection molded frame member) having a central annular portion **304** and a plurality (e.g., three) of extension portions or members **306** extending radially outwardly from the annular portion **304**. The extension members **306** can be coupled to a second or proximal frame member **308**. A plurality of curved side panels **310** having two rows of cutting teeth **312** can be coupled to the second frame member **308**, for example, by injection molding the second frame member around the side panels and a dome panel **314** as described above. In certain embodiments, the side panels **310** and the dome panel **314** of the cutting tool **300** can comprise engagement members similar to the engagement members **126/154** described above. In certain embodiments, the first frame member **302** can be coupled to the second frame member **308** by ultrasonic welding, or by any other coupling structure/method. In certain embodiments, the frame can be a unitary body in which the frame member **302** and the frame member **308** are formed in the same molding operation.

In certain embodiments, the first frame member **302** can provide a plurality of options for coupling (e.g., quick-connect coupling) to a drive shaft (e.g., a reamer shaft). In certain embodiments, the interior volume of the cutting tool **300** can be configured to accommodate a specified volume of reamed bone/bone shavings/cuttings according to the particular procedure to be performed. In certain embodiments, the first and/or second frame members can be color coded to indicate a specified size of the cutting tool.

FIG. **33** illustrates an exploded view of the hemispherical cutting tool **300**. In the illustrated embodiment, the side panels **310** can comprise a respective lobe **320** at the upper or distal end of the side panels (e.g., relative to a use orientation of the cutting tool). The lobes **320** can extend from the main body of the side panels **310** in the direction of the pole of the cutting tool. In certain embodiments, the lobes **320** can be wholly offset to one side of a longitudinal axis **322** of the side panels **310**. In certain embodiments, the longitudinal axis **322** can pass through openings **324** (e.g., datum openings) of the side panels. The lobes **320** can include cutting teeth **312** (FIG. **32**). Thus, the row of cutting teeth **312** aligned with the lobe **320** can include an additional cutting tooth relative to the other row of cutting teeth on each panel.

The dome panel **314** can also comprise a plurality of circumferentially spaced apart lobes **326** extending outwardly from a round or circular main body of the dome panel **314**. A plurality of the lobes **326**, such as all of the lobes **326** or a subset of the lobes, can comprise cutting teeth **312**. When the side panels **310** and the dome panel **314** are coupled to the frame **302/308**, the side panels **310** be oriented such that lobes **320** of the side panels are received between lobes **326** of the dome panel **314** (e.g., the lobes **320** of the side panels alternate with the lobes **326** of the dome panel in the circumferential direction). Two side panels, such as side panels **310**A and **310**B in FIG. **33** can be arranged with their lobes **320** adjacent each other, and those two lobes **320** can be received between a pair of lobes **326** of the dome panel **314**. The cutting teeth **312** of the panels **310**A and **310**B can also be oriented in opposite circumferential directions.

The frame **302/308** can comprise a plurality of openings or windows **328** defined by circumferentially spaced apart, longitudinally extending frame members **330**. The openings **328** can be covered by respective side panels **310**. The frame **302/308** can also comprise a polar opening **332**, which can be covered by the dome panel **314** in the assembled state.

Any of the features/configurations of the cutting tool **100** and/or the cutting tool **300** can be used or applicable in combination with any of the cutting tool embodiments described herein. In certain embodiments, any of the cutting tool embodiments described herein can be packaged together with any of a variety of other accessories including drive shafts, guides, etc., in a sterile kit or surgical pack.

In view of the many possible embodiments to which the principles of the disclosure may be applied, it should be recognized that the illustrated embodiments are only examples and should not be taken as limiting the scope of the claimed subject matter. Rather, the scope of the claimed subject matter is at least as broad as the following claims and their equivalents.

The invention claimed is:

1. A hemispherical cutting tool, comprising:

a frame having a first end portion and a second end portion, and defining an axis of rotation of the hemispherical cutting tool;

a plurality of curved side panels coupled to the frame and arranged about the axis of rotation of the cutting tool, the curved side panels comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly into the frame from edge portions of the curved side panels and bent in a direction toward a hollow interior of the hemispherical cutting tool; and

a dome panel coupled to the second end portion of the frame such that the cutting tool has a hemispherical shape, the dome panel comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly from edge portions of the dome panel into the frame and bent in a direction toward the hollow interior of the hemispherical cutting tool;

wherein the frame is injection molded around the curved side panels and the dome panel such that the engagement members of the curved side panels and the dome panel are embedded in the injection molded frame.

2. The hemispherical cutting tool of claim **1**, wherein side edge portions and distal edge portions of the curved side panels comprise engagement members.

3. The hemispherical cutting tool of claim **1**, wherein the engagement members of the curved side panels comprise T-shaped members.

4. The hemispherical cutting tool of claim **1**, wherein the frame comprises a first polymeric frame member comprising an annular body, and a second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member.

5. The hemispherical cutting tool of claim **4**, wherein one of the first or second polymeric frame members comprises a plurality of coupling portions configured to be received in openings defined in the other of the first or second polymeric frame members.

6. The hemispherical cutting tool of claim **1**, wherein:

the cutting teeth of the curved side panels are arranged in columns; and cutting edges of the cutting teeth are longitudinally offset from each other in adjacent columns and at least partially overlap with each other in the circumferential direction.

7. The hemispherical cutting tool of claim **1**, wherein:

the cutting teeth of the curved side panels are arranged in columns;

the cutting teeth of a central column of cutting teeth of each curved side panel are aligned with a central axis of the curved side panel; and

cutting teeth of columns of cutting teeth that are circumferentially offset from the central column of cutting teeth are angled toward the central column of cutting teeth.

8. The hemispherical cutting tool of claim **1**, wherein:

the cutting teeth of the curved side panels comprise a long dimension and a short dimension; and

the long dimensions of the cutting teeth are oriented longitudinally on a hemispherical surface of the cutting tool.

9. The hemispherical cutting tool of claim **1**, wherein the axis of rotation of the hemispherical cutting tool intersects a cutting tooth of the plurality of cutting teeth of the dome panel.

10. The hemispherical cutting tool of claim **1**, wherein the dome panel comprises a plurality of lobes separated by concave edge portions, each of the lobes comprising an engagement member.

11. A method of making the hemispherical cutting tool of claim **1**, comprising:

situating the dome panel and the plurality of curved side panels in a mold; and

injecting a polymeric material into the mold to form at least a portion of the frame.

12. A method, comprising cutting bone with the hemispherical cutting tool of claim **1**.

13. The hemispherical cutting tool of claim **1**, wherein the engagement members of the curved side panels extend radially inwardly into the frame toward the hollow interior of the hemispherical cutting tool.

14. A hemispherical cutting tool, comprising:

a polymeric frame comprising a first polymeric frame member coupled to a second polymeric frame member and defining an axis of rotation of the hemispherical cutting tool, the first polymeric frame member comprising an annular body and defining a first end portion of the frame, the second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member and converging toward a second end portion of the polymeric frame;

a metal dome panel coupled to the second polymeric frame member at the second end portion of the polymeric frame, the metal dome panel comprising a plurality of cutting teeth; and

a plurality of curved metal side panels coupled to the polymeric frame and arranged about the axis of rotation of the hemispherical cutting tool.

15. The hemispherical cutting tool of claim **14**, wherein the curved metal side panels comprise a plurality of engagement members extending inwardly from edge portions of the curved metal side panels into the second polymeric frame member in a direction toward a hollow interior of the hemispherical cutting tool.

16. The hemispherical cutting tool of claim **15**, wherein side edge portions and distal edge portions of the curved metal side panels comprise engagement members.

17. The hemispherical cutting tool of claim **15**, wherein the metal dome panel comprises a plurality of engagement members extending from edge portions of the metal dome panel inwardly into the second polymeric frame member in a direction toward the hollow interior of the hemispherical cutting tool.

18. The hemispherical cutting tool of claim **15**, wherein the engagement members of the curved metal side panels comprise T-shaped members.

19. The hemispherical cutting tool of claim **15**, wherein the frame is injection molded around the curved metal side panels and the metal dome panel such that the engagement members of the curved metal side panels and the metal dome panel are embedded in the injection molded frame.

20. The hemispherical cutting tool of claim **14**, wherein one of the first or second polymeric frame members comprises a plurality of coupling portions configured to be received in openings defined in the other of the first or second polymeric frame members.

21. The hemispherical cutting tool of claim **14**, wherein:

the cutting teeth of the curved metal side panels comprise a long dimension and a short dimension; and

the long dimensions of the cutting teeth are oriented longitudinally on a hemispherical surface of the cutting tool.

22. The hemispherical cutting tool of claim **14**, wherein the axis of rotation of the hemispherical cutting tool intersects a cutting tooth of the plurality of cutting teeth of the metal dome panel.

23. The hemispherical cutting tool of claim **14**, wherein the metal dome panel comprises a plurality of lobes separated by concave edge portions, each of the lobes comprising an engagement member.

24. A hemispherical cutting tool, comprising:

a frame comprising a first polymeric frame member coupled to a second polymeric frame member and defining an axis of rotation of the hemispherical cutting tool, the first polymeric frame member comprising an annular body and defining a first end portion of the frame, the second polymeric frame member comprising a plurality of curved extension members coupled to the annular body of the first polymeric frame member and converging toward a second end portion of the polymeric frame;

a plurality of curved side panels coupled to the frame and arranged about the axis of rotation of the cutting tool, the curved side panels comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly into the frame from edge portions of the curved side panels in a direction toward a hollow interior of the hemispherical cutting tool; and

a dome panel coupled to the second end portion of the frame such that the cutting tool has a hemispherical shape, the dome panel comprising a plurality of cutting teeth and a plurality of engagement members extending inwardly from edge portions of the dome panel into the frame in a direction toward the hollow interior of the hemispherical cutting tool;

wherein the second polymeric frame member is injection molded around the curved side panels and the dome panel such that the engagement members of the curved side panels and the dome panel are embedded in the second polymeric frame member.

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