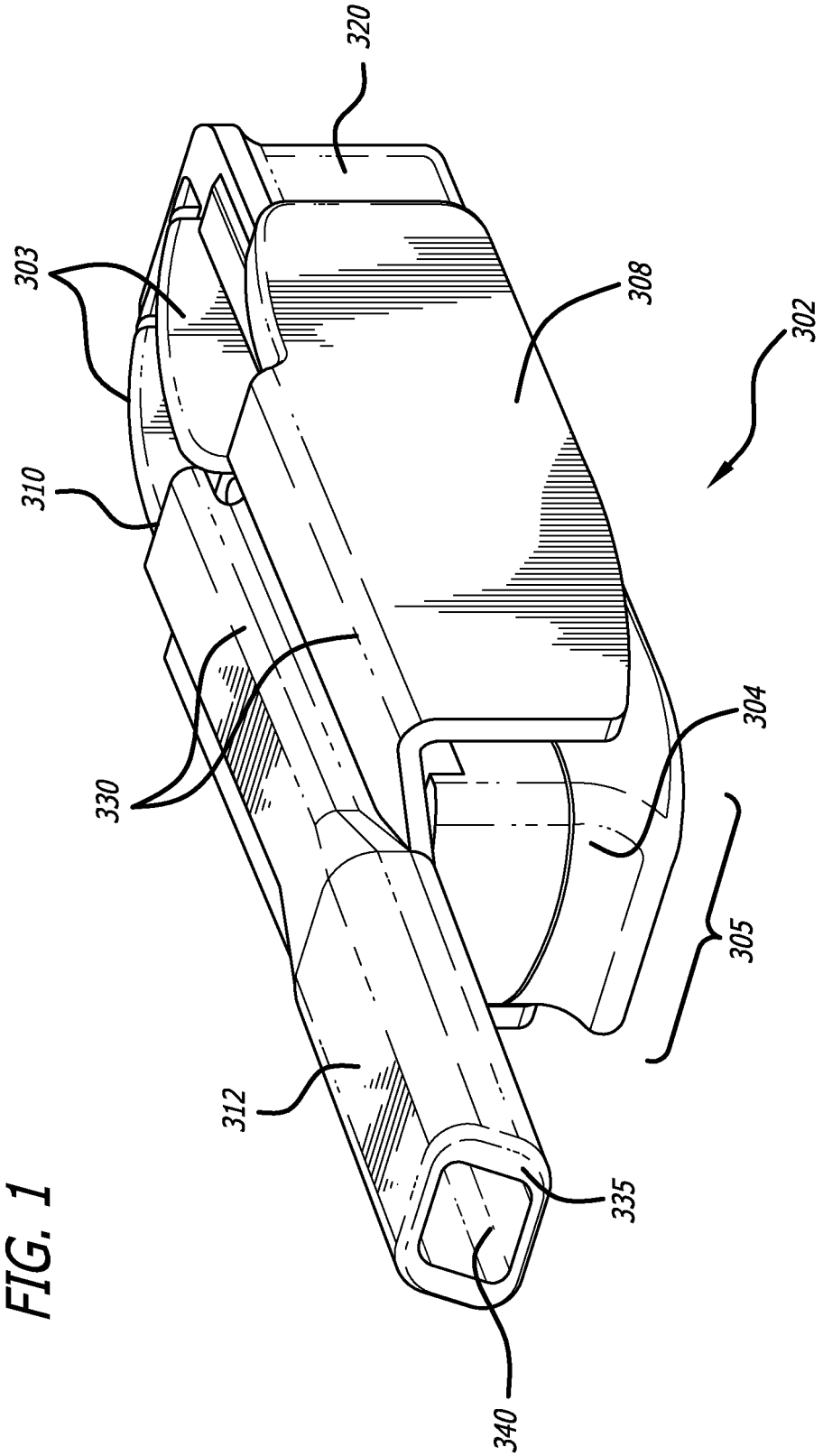


FIG. 1

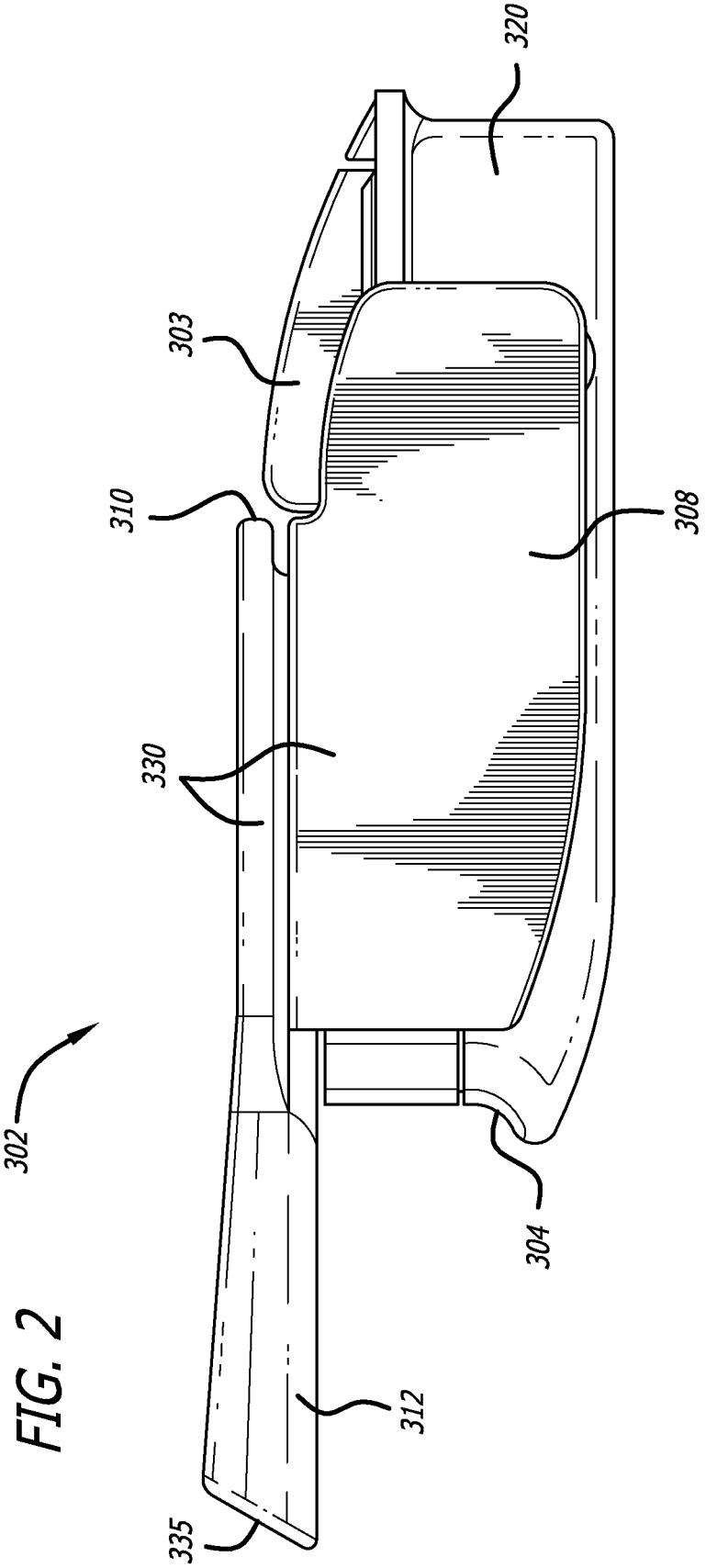


FIG. 2

FIG. 3

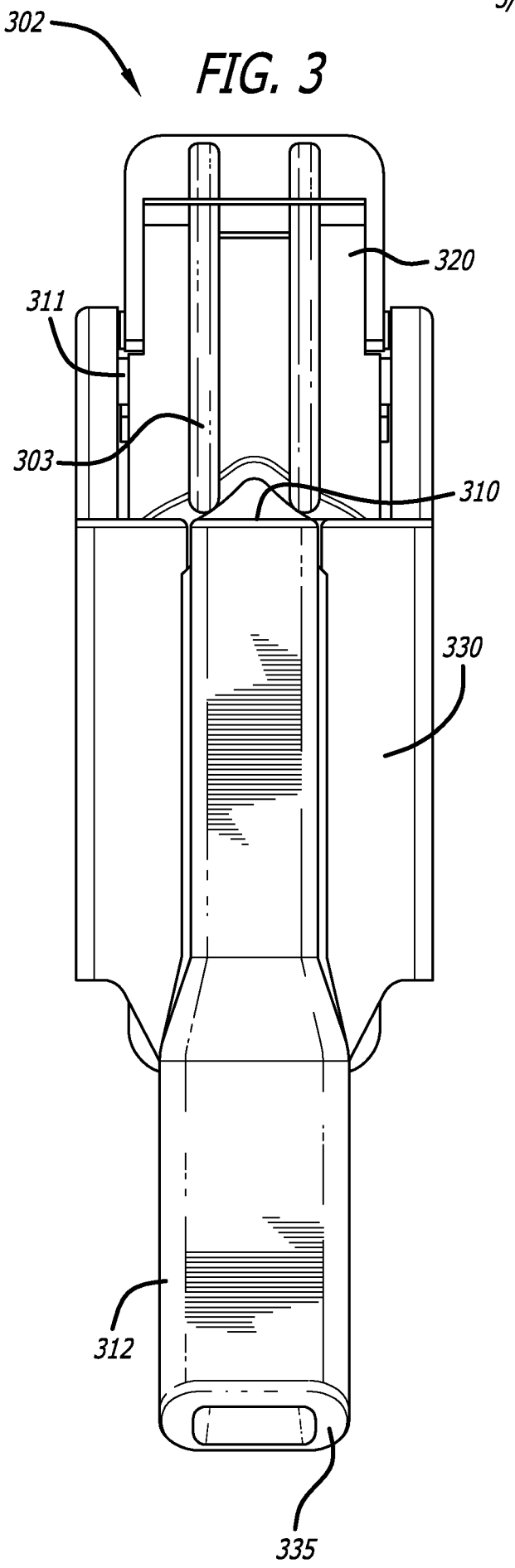


FIG. 4

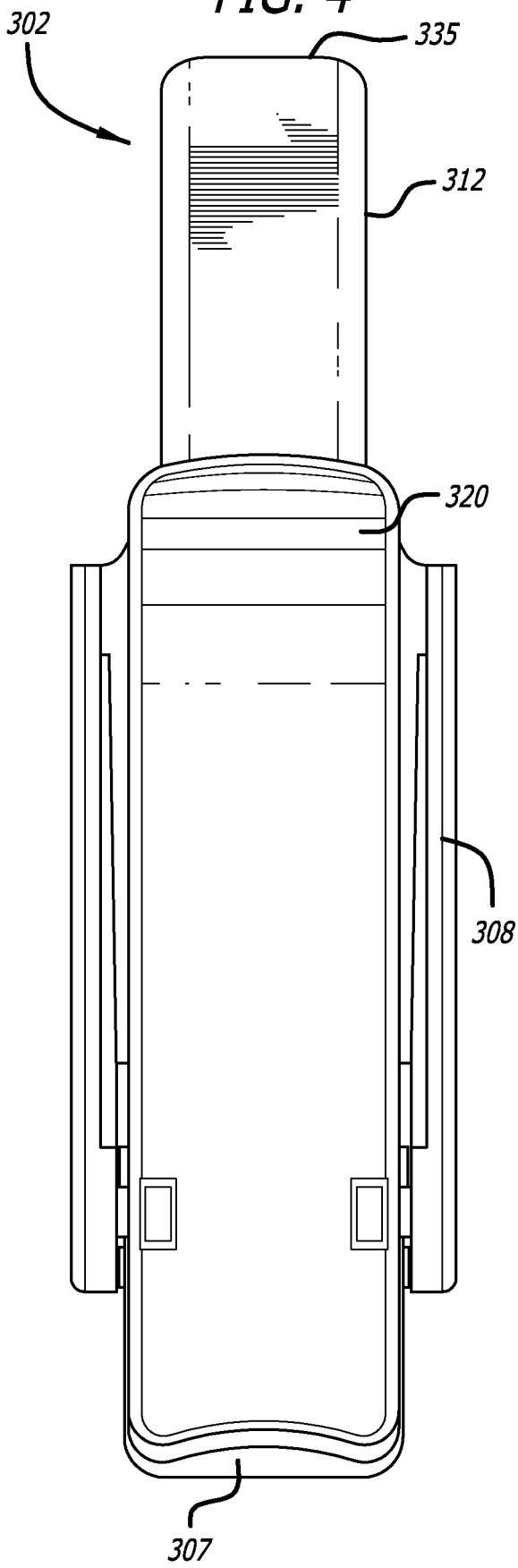


FIG. 5

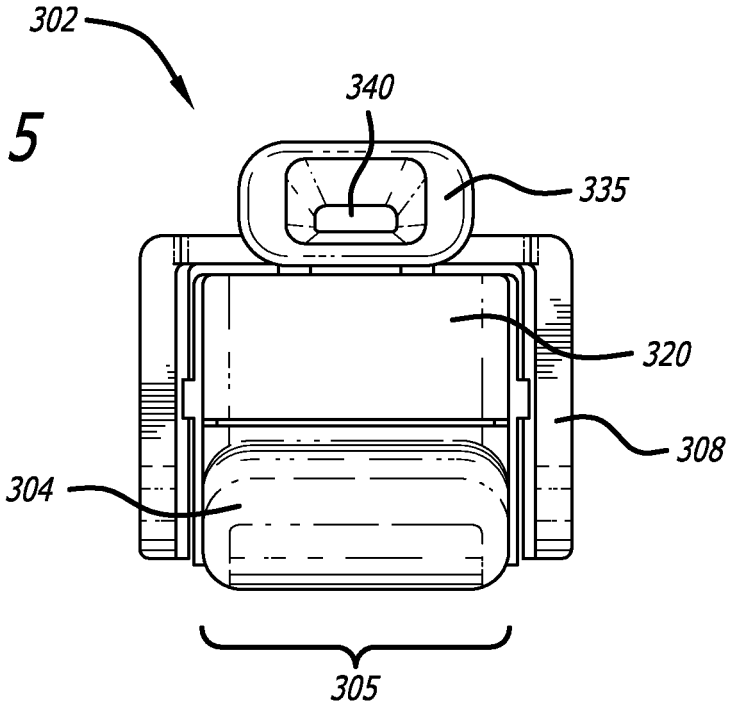


FIG. 6

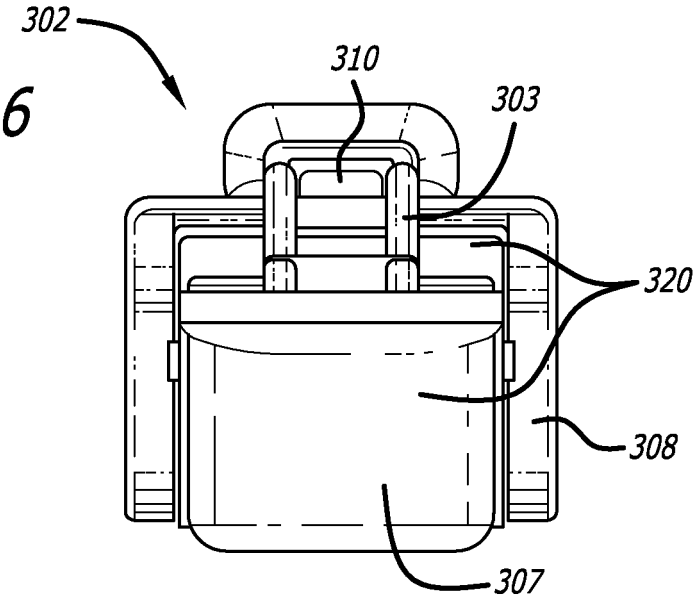


FIG. 7

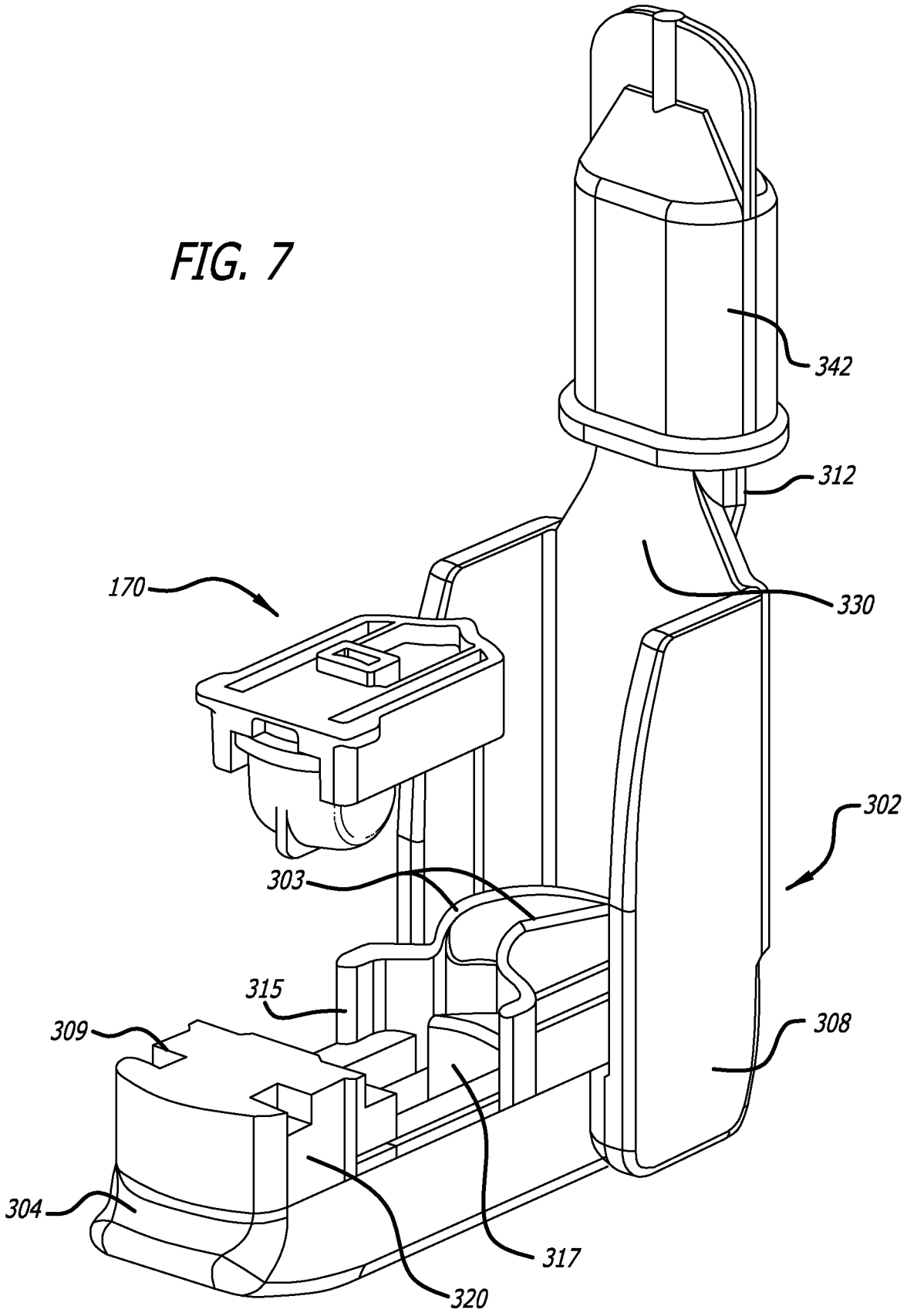
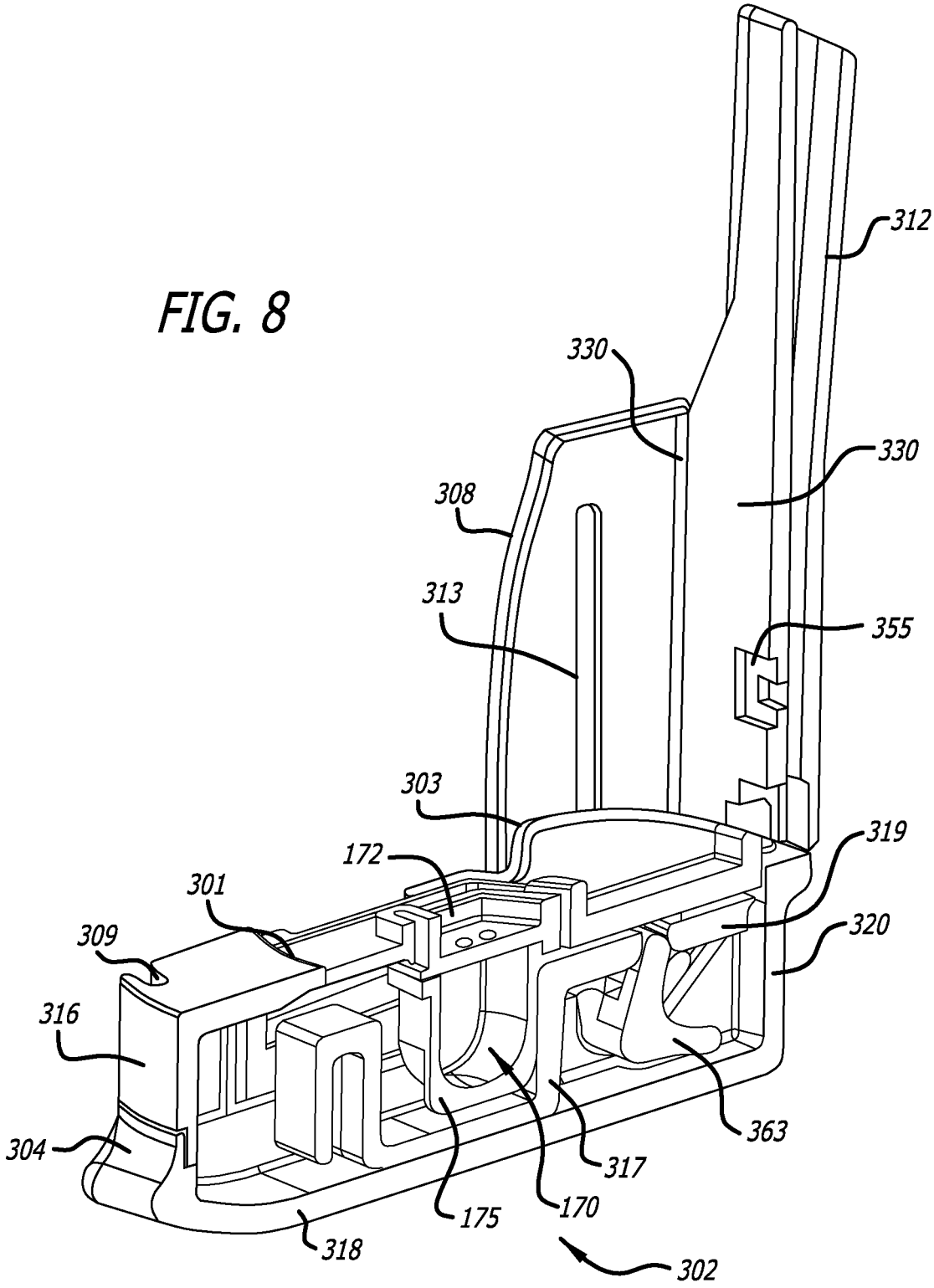


FIG. 8


312
330
330
308
313
355
303
319
172
301
320
309
316
363
304
317
175
170
318
302

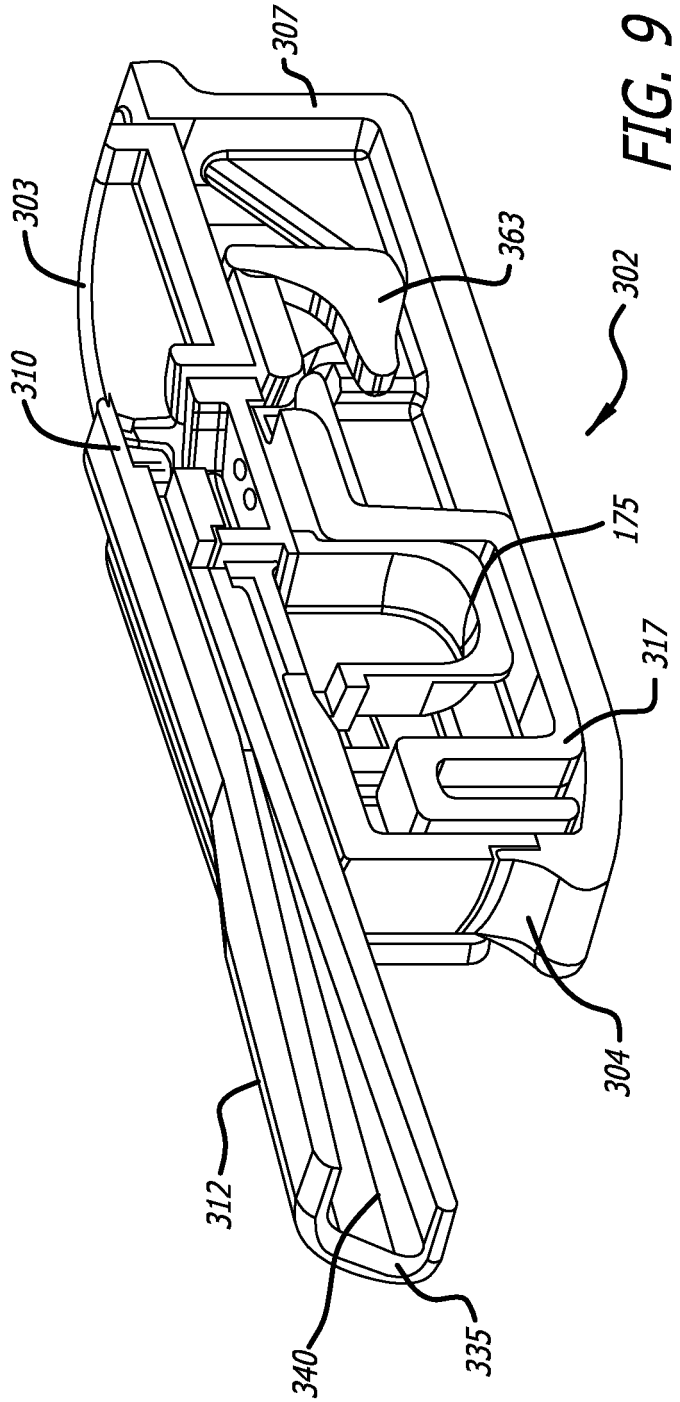
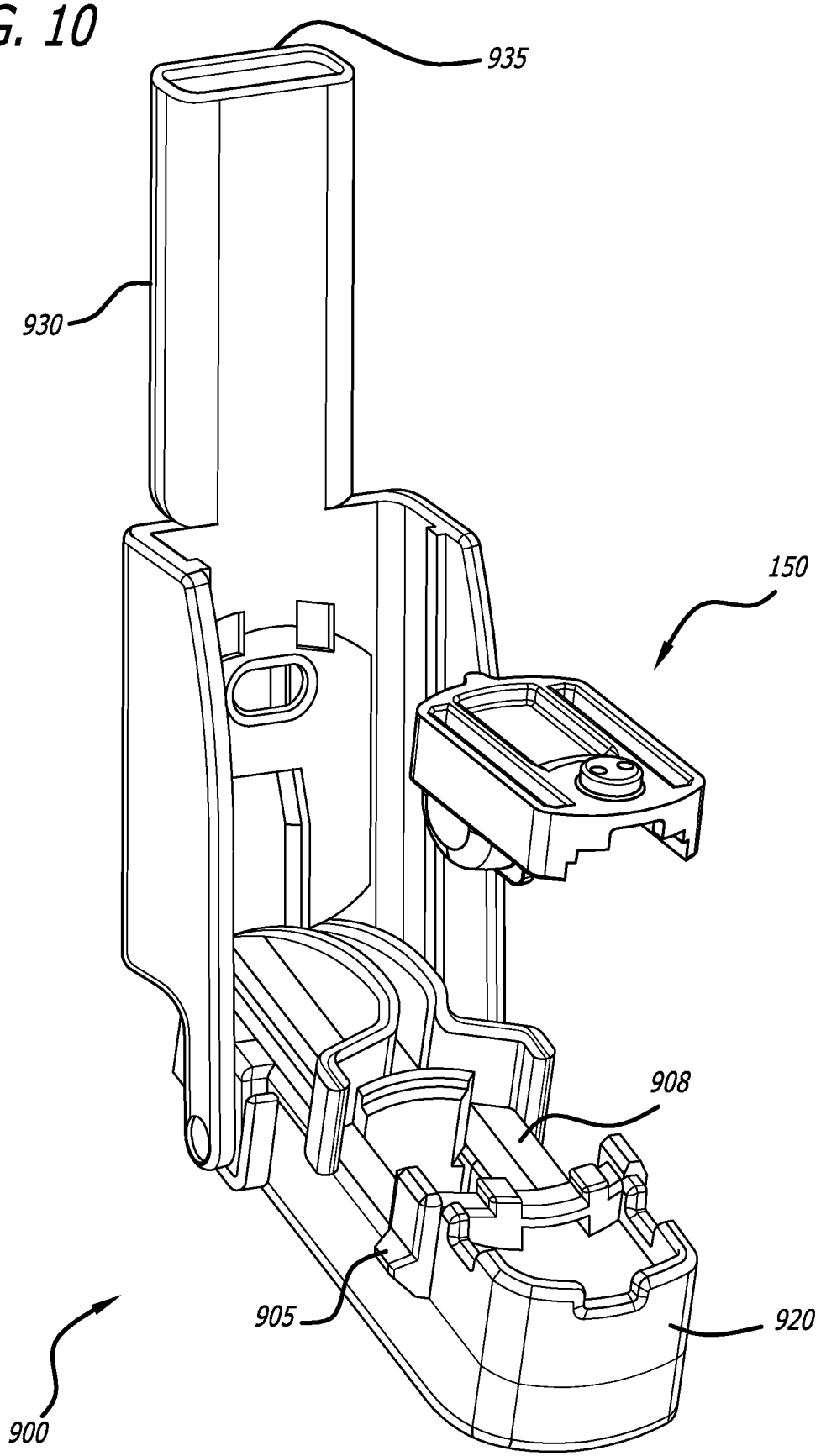


FIG. 9

FIG. 10



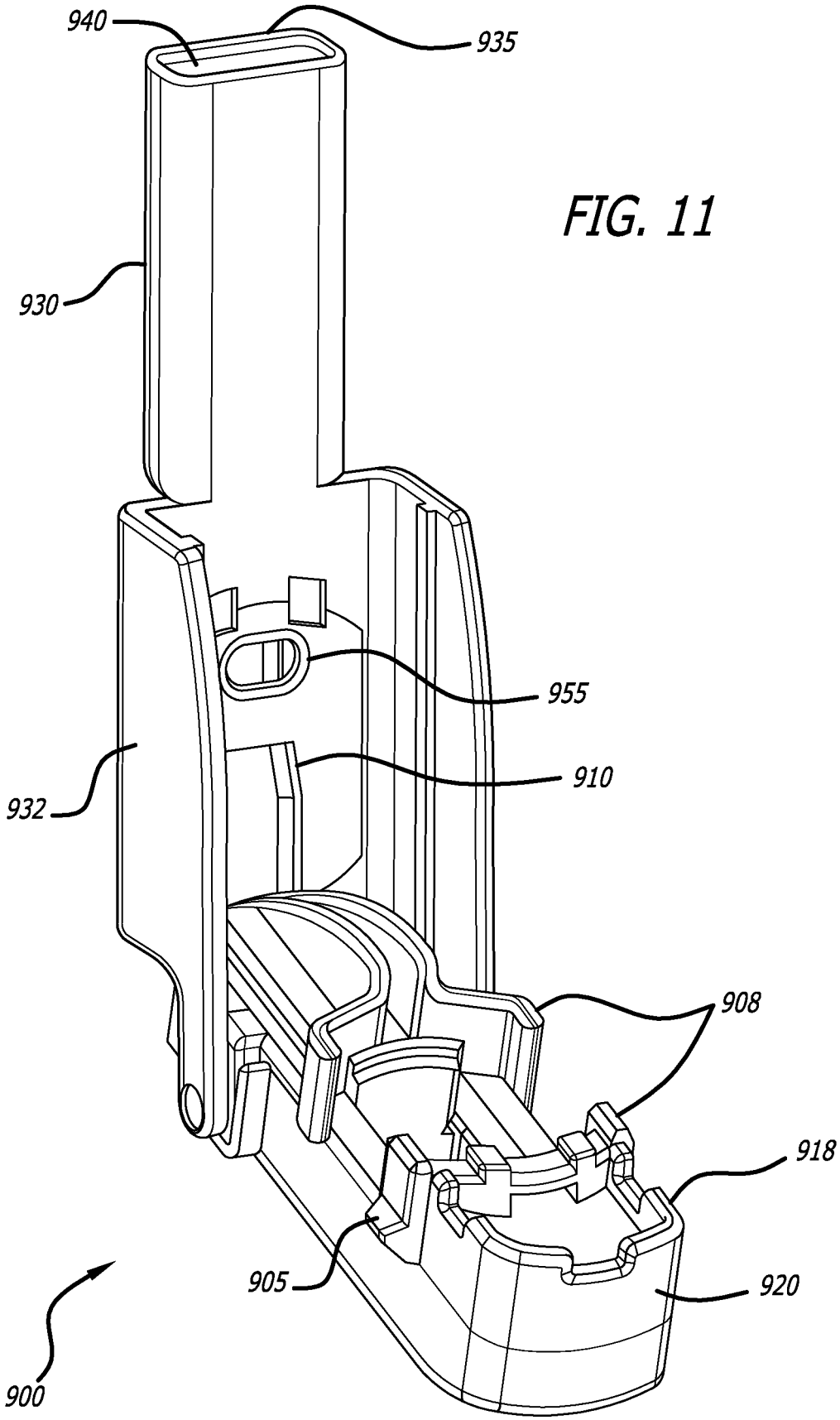


FIG. 11

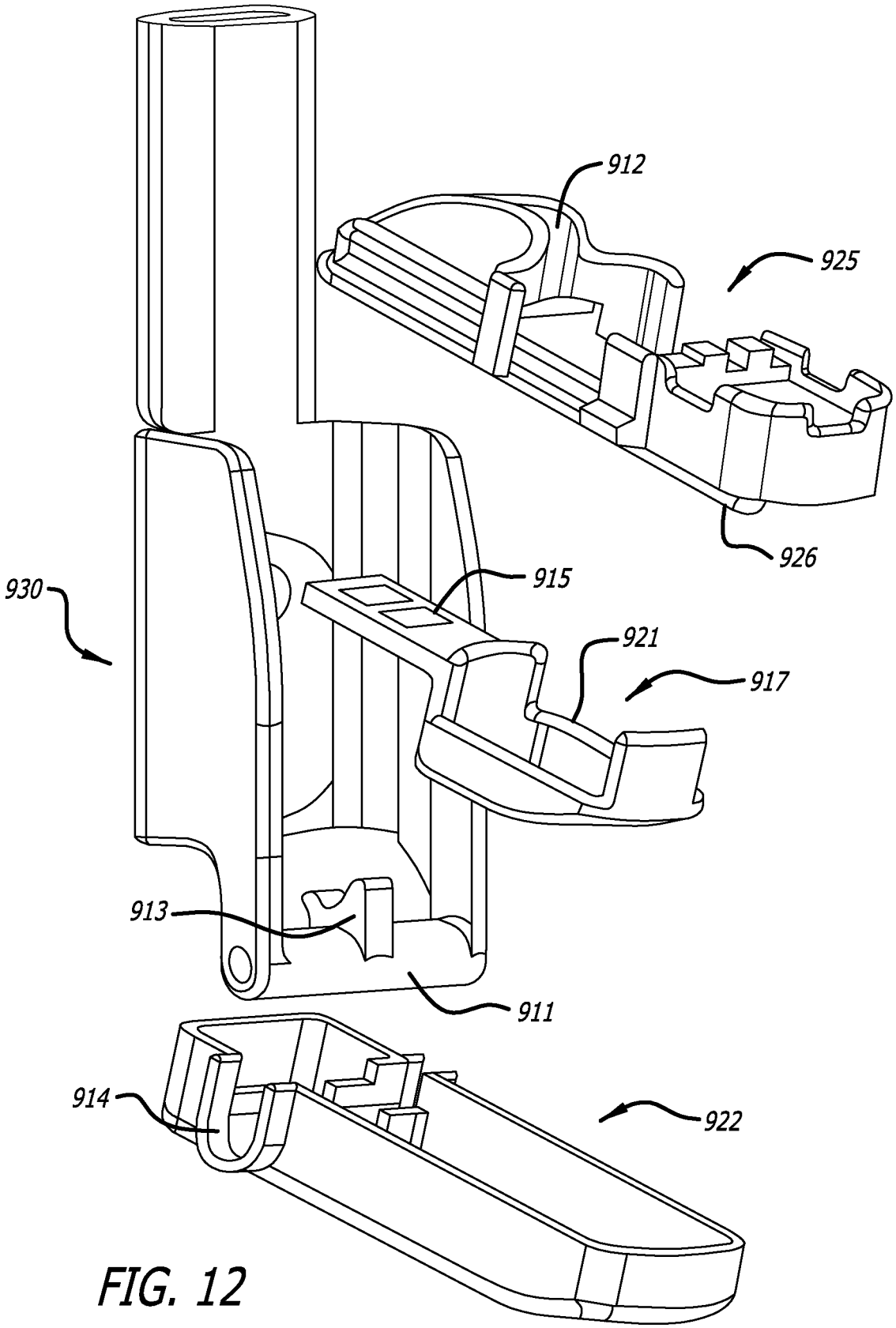


FIG. 12

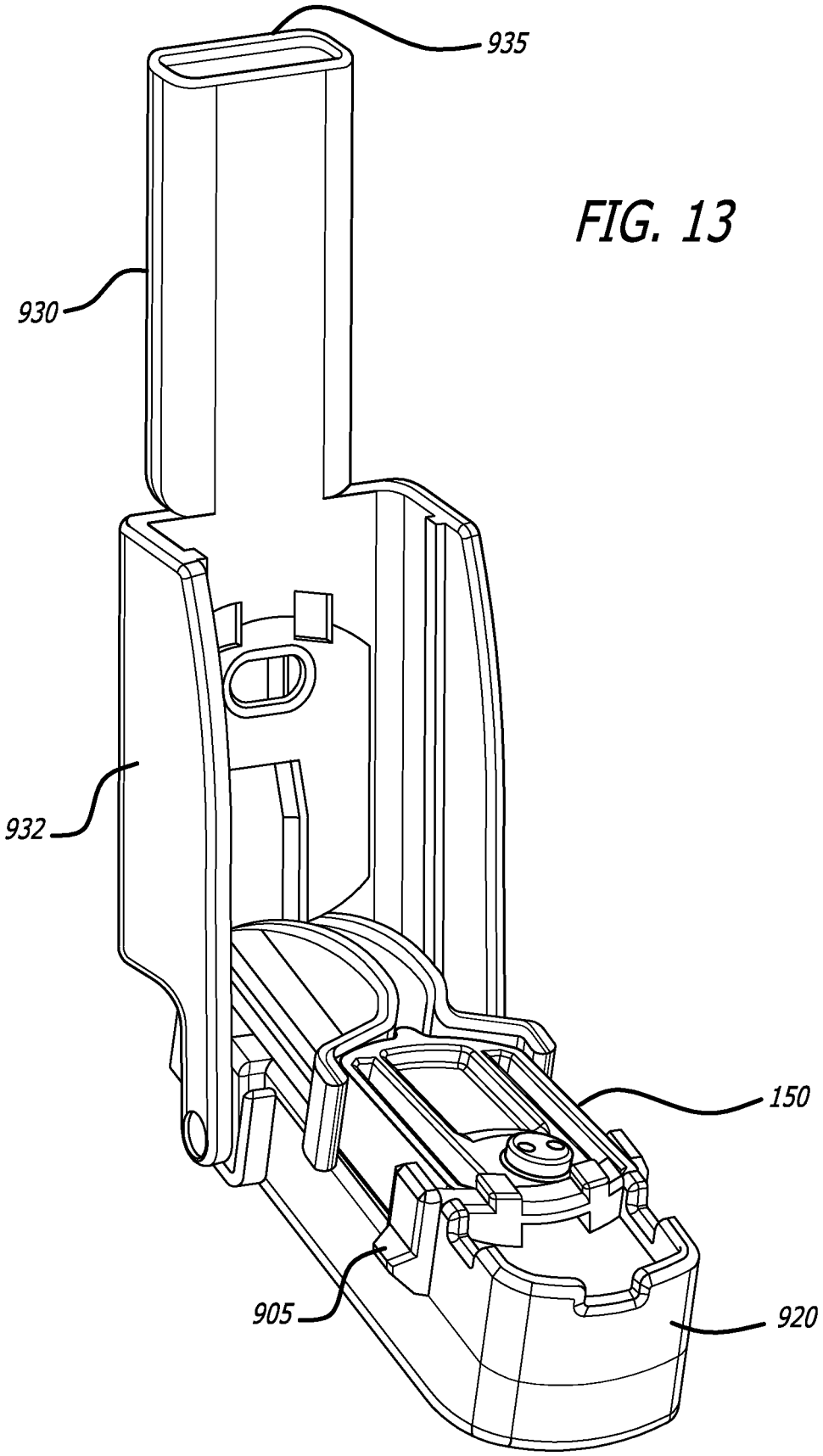


FIG. 13

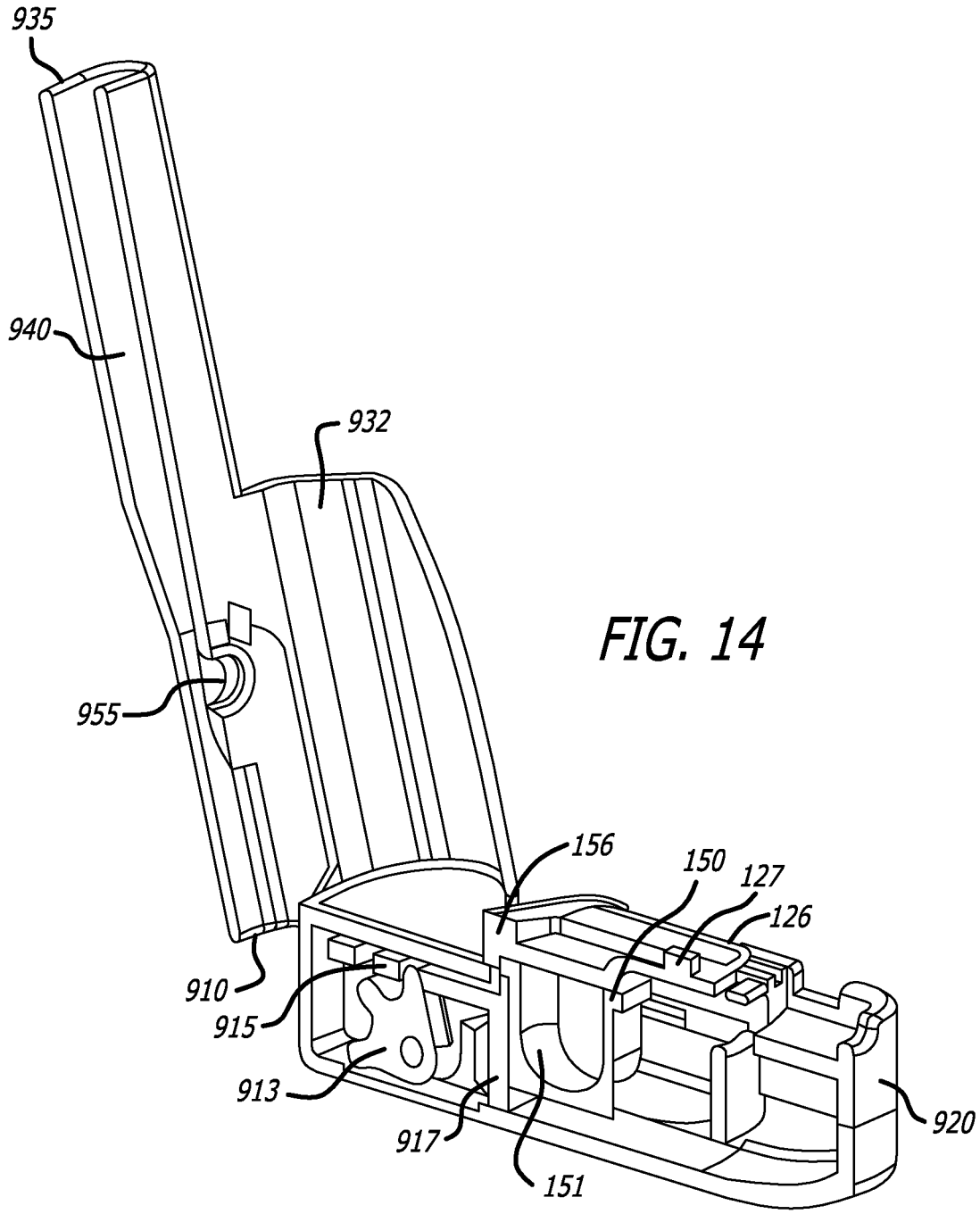


FIG. 14

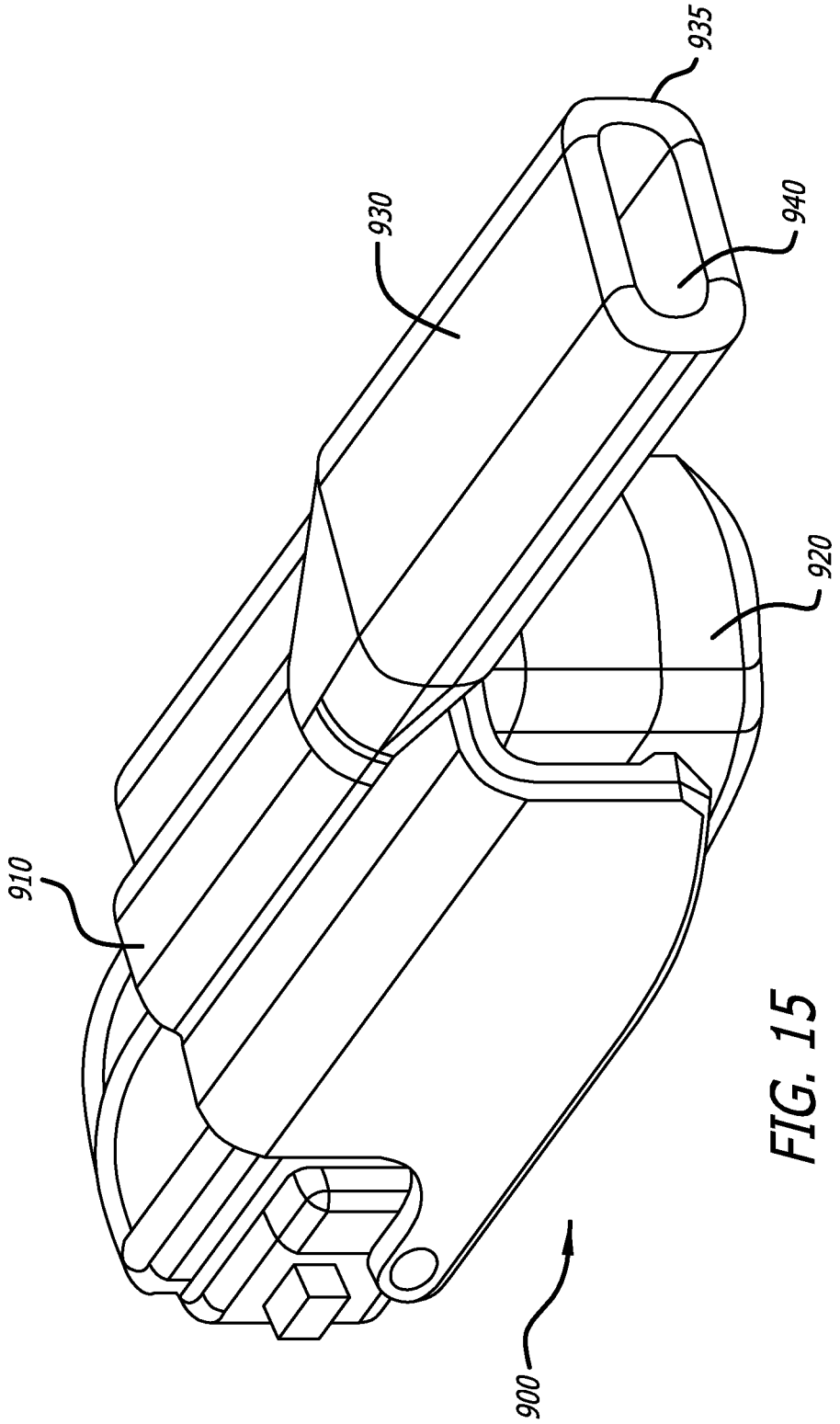


FIG. 15

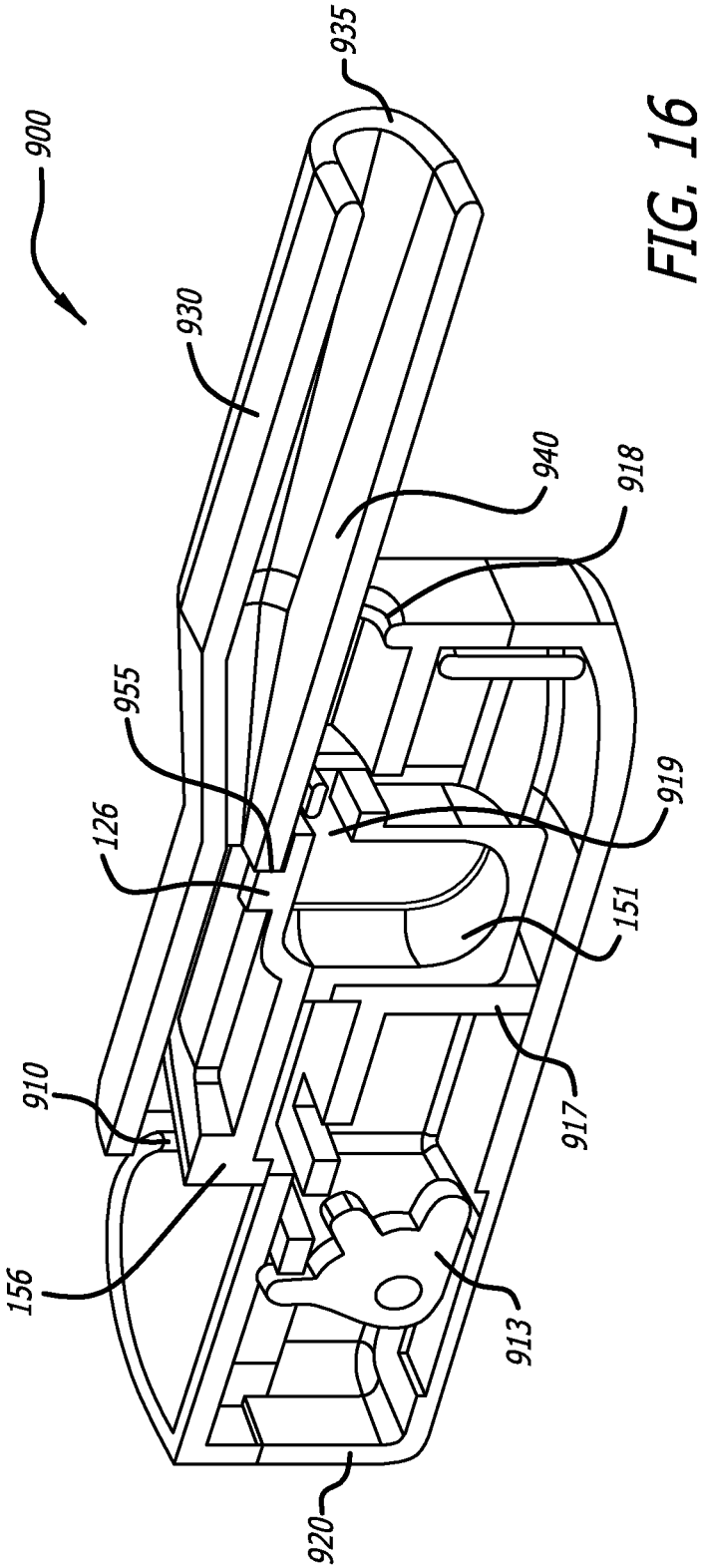


FIG. 16

FIG. 17

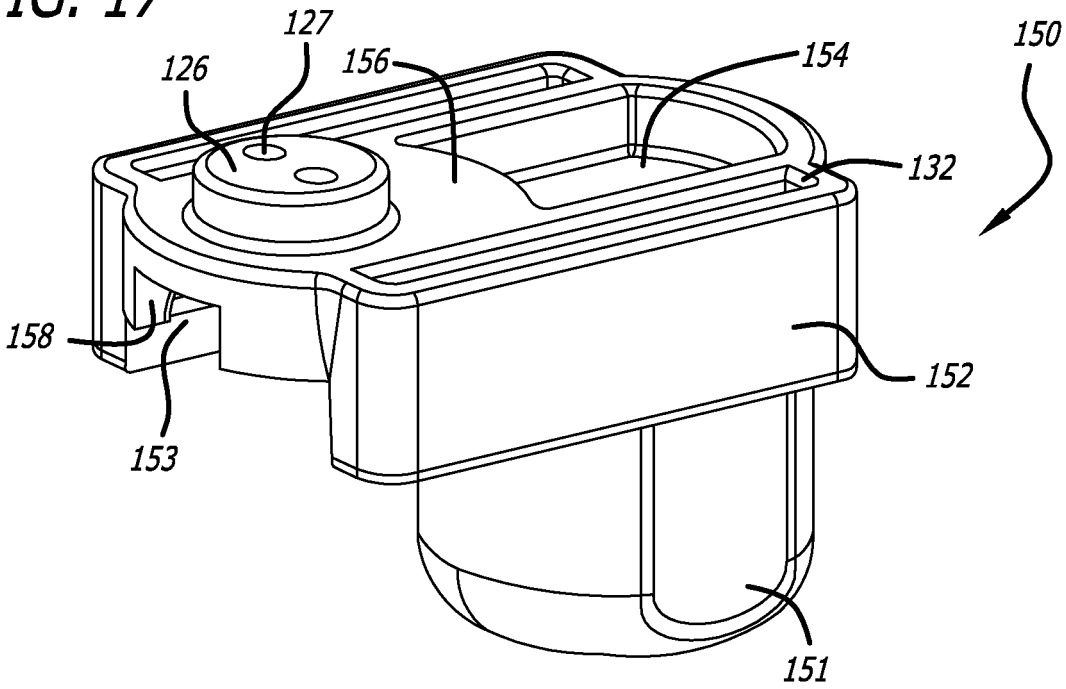

127
126
156
154
150
132
158
152
153
151

FIG. 18

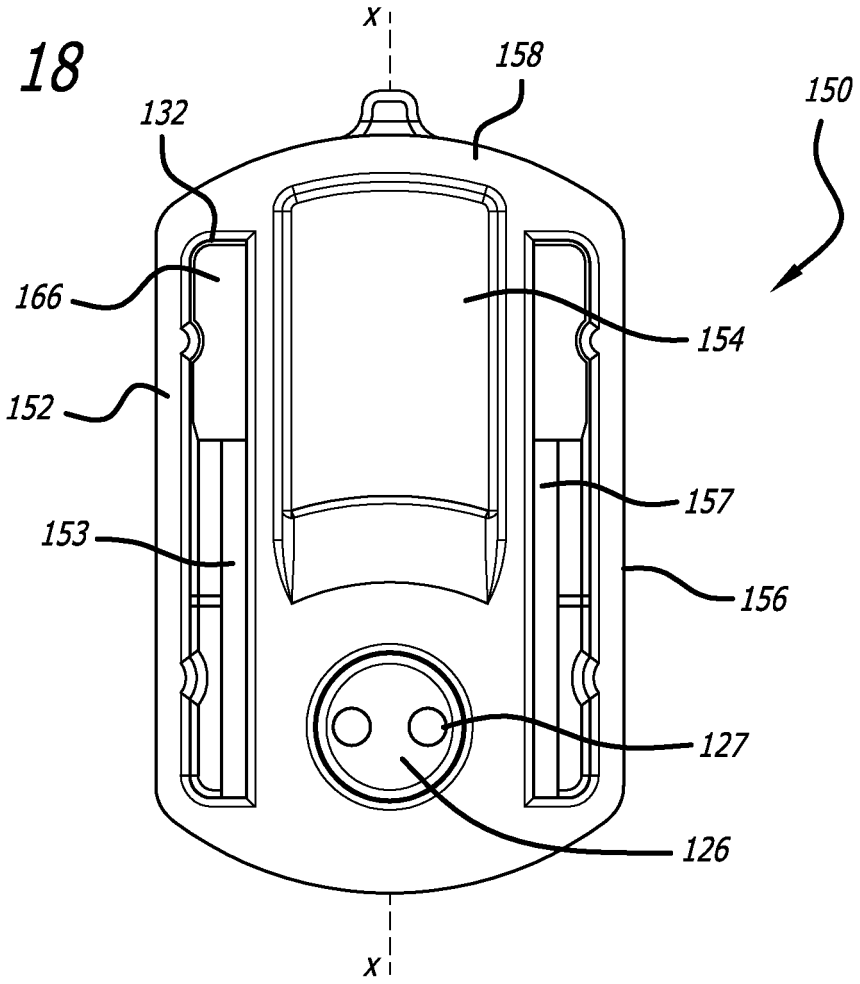

x
158
132
150
166
154
152
157
153
156
127
126
x

FIG. 19

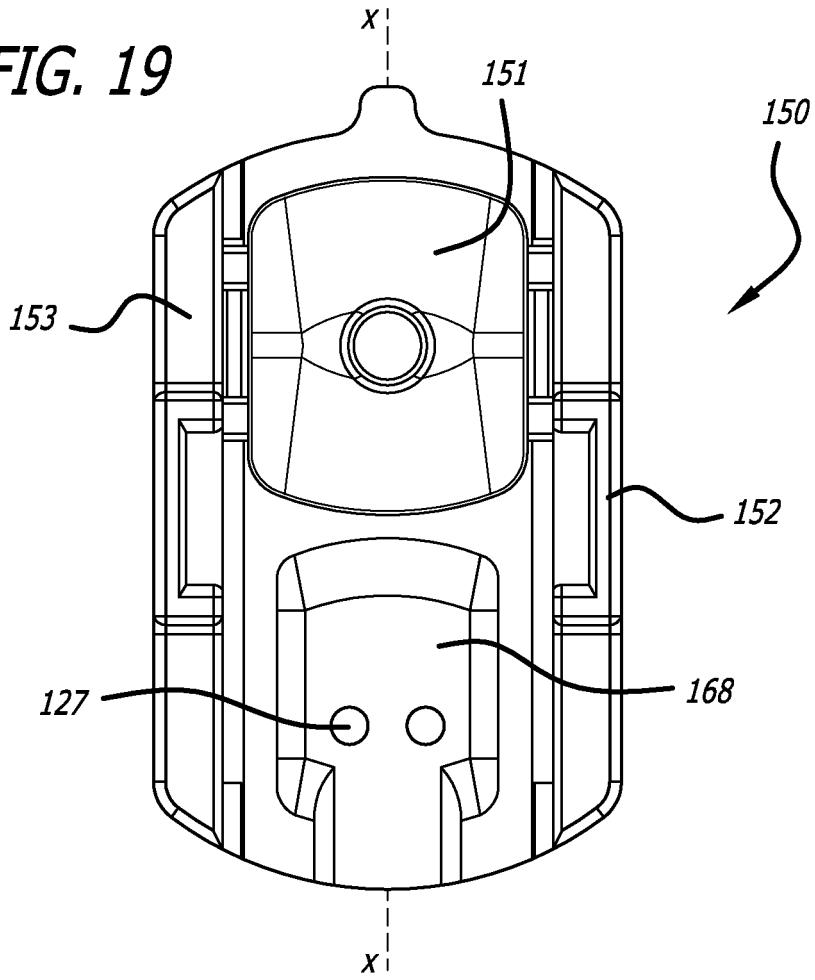

X
151
150
153
152
127
168
X

FIG. 20

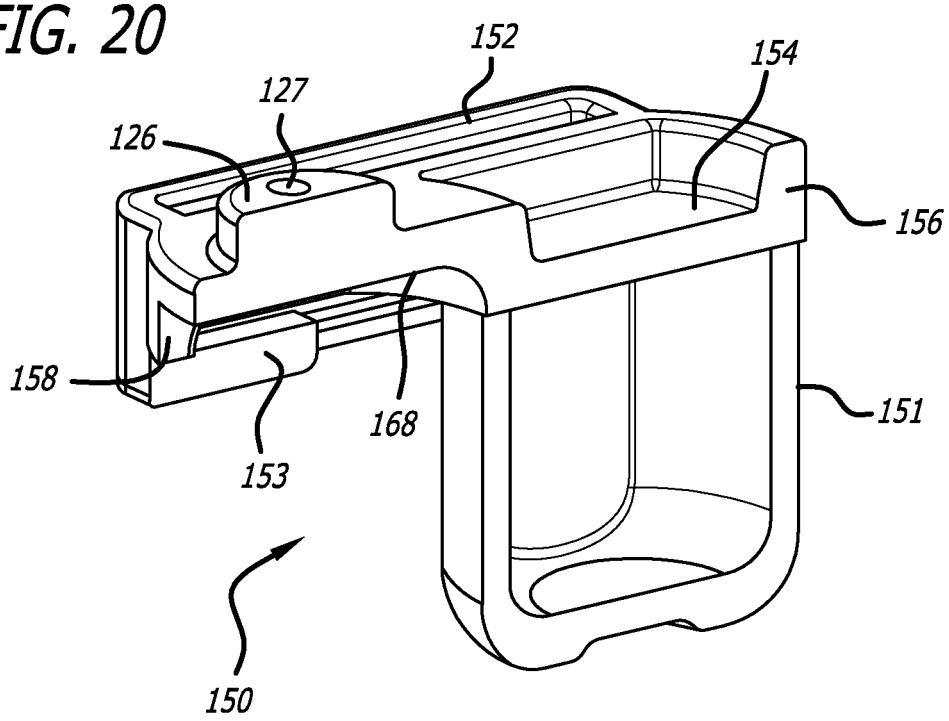

152
154
127
126
156
158
168
151
153
150

FIG. 21

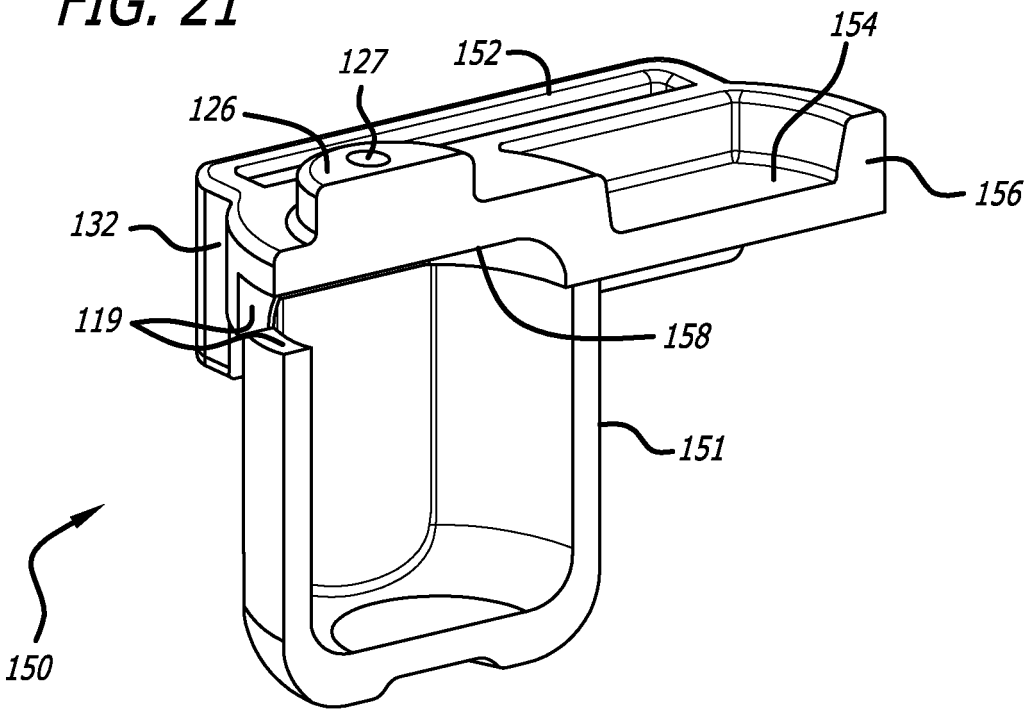
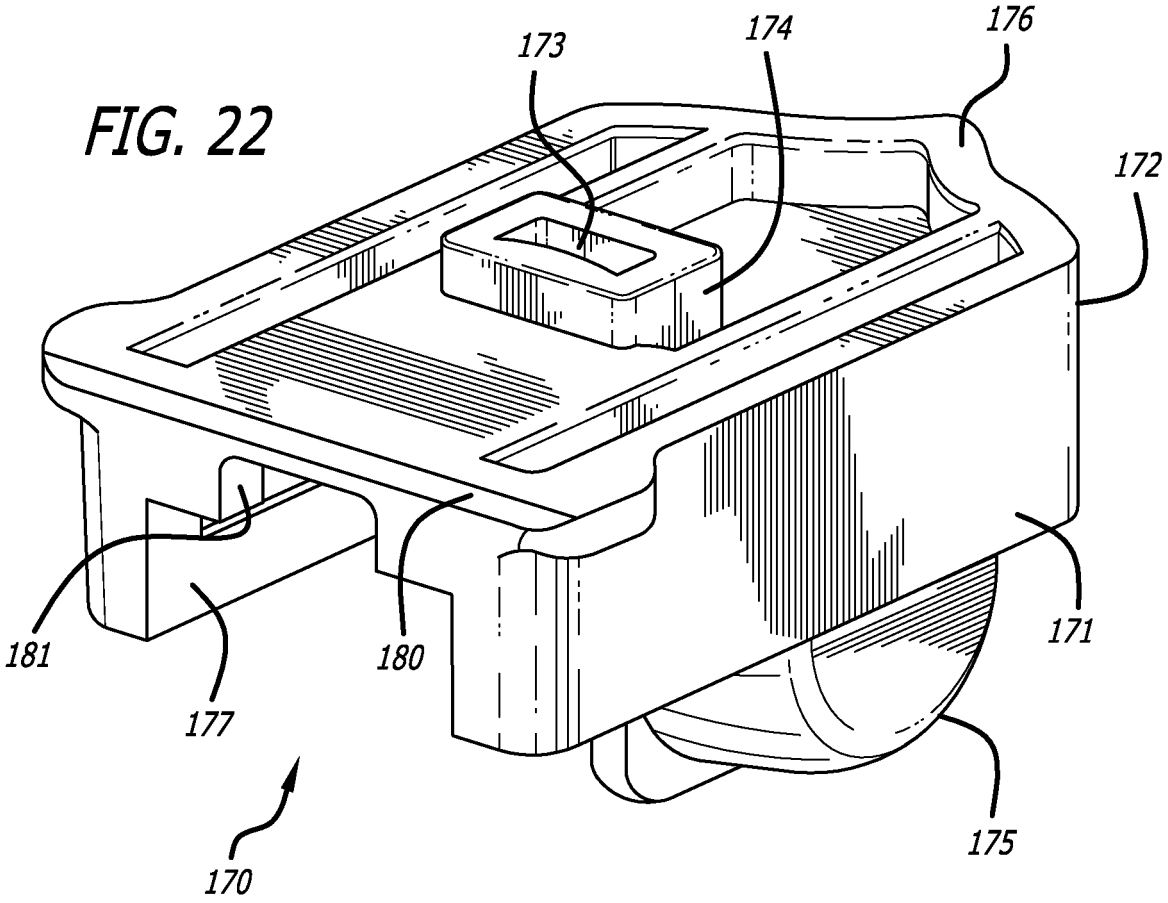

154
152
127
126
156
132
119
158
151
150

FIG. 22


173
174
176
172
181
180
171
177
175
170

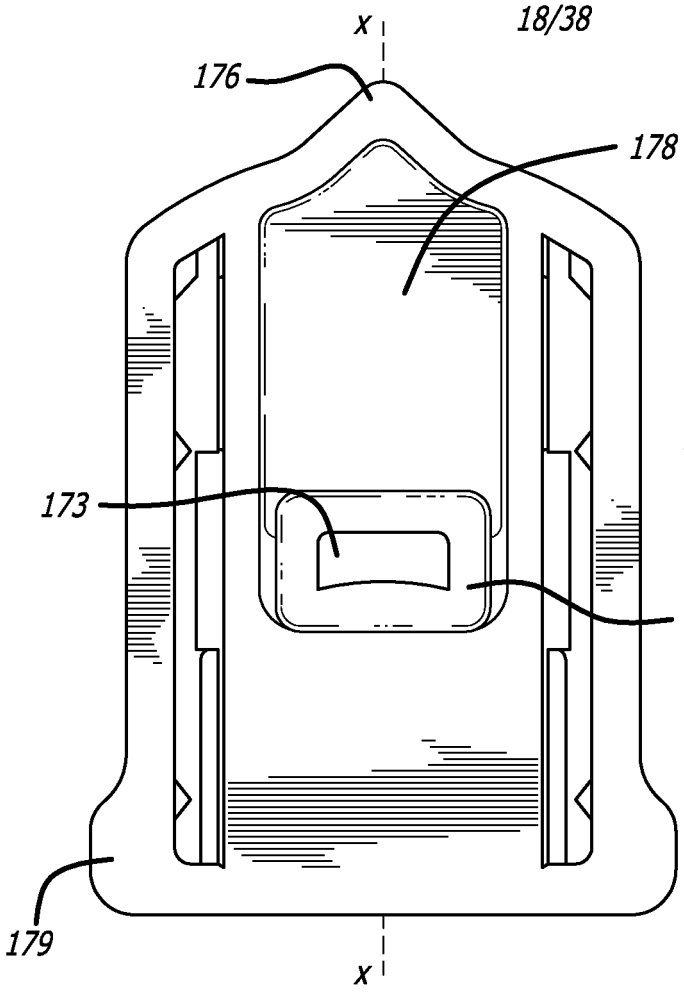


FIG. 23

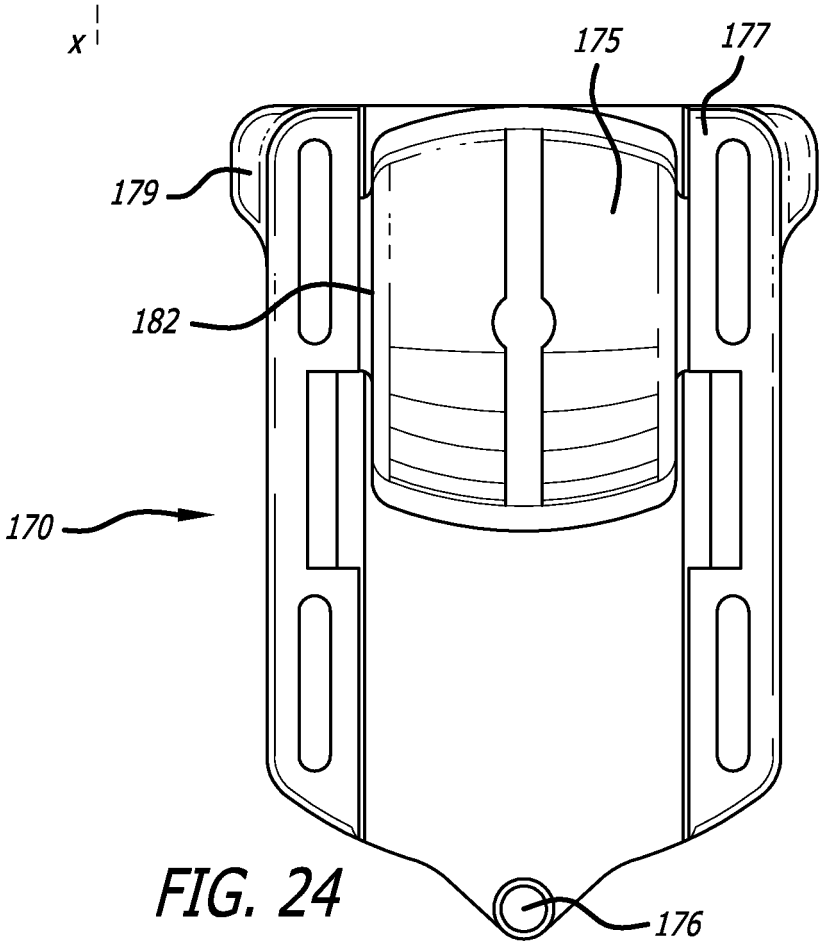


FIG. 24

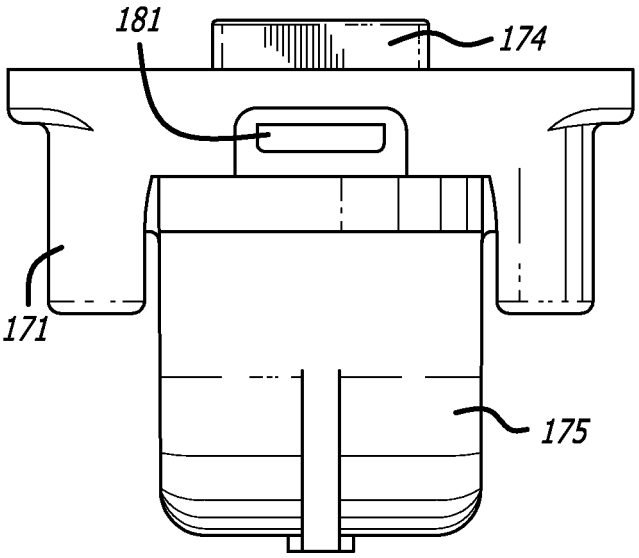


FIG. 25

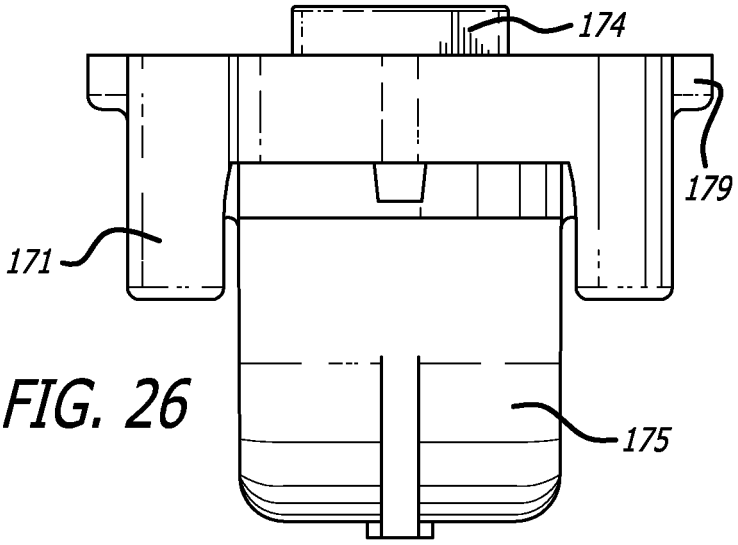


FIG. 26

FIG. 27

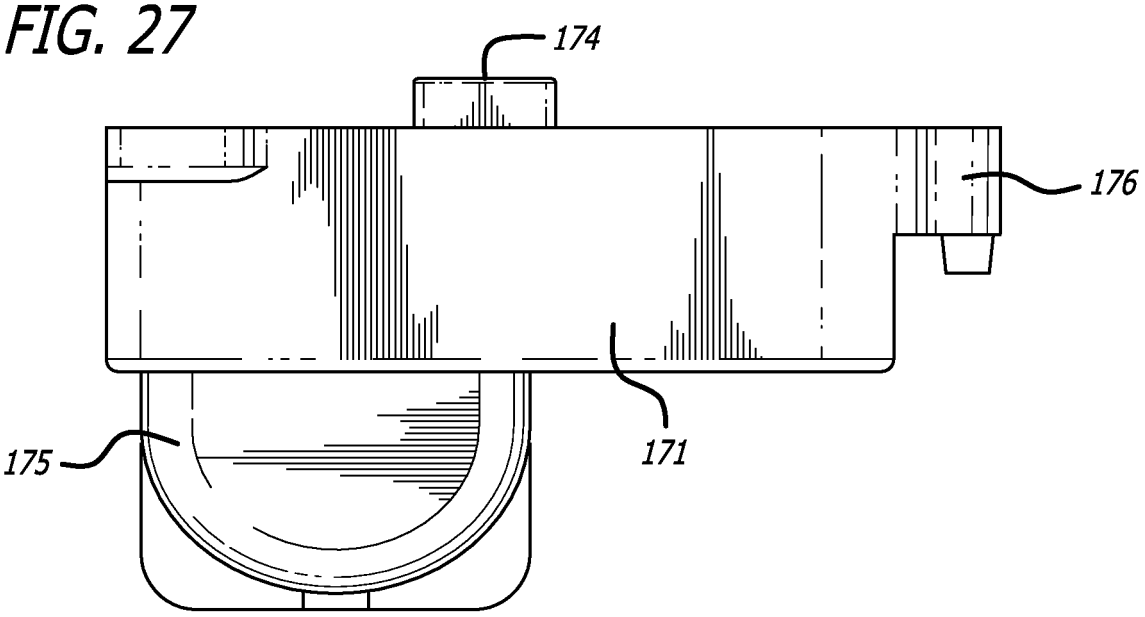


FIG. 28

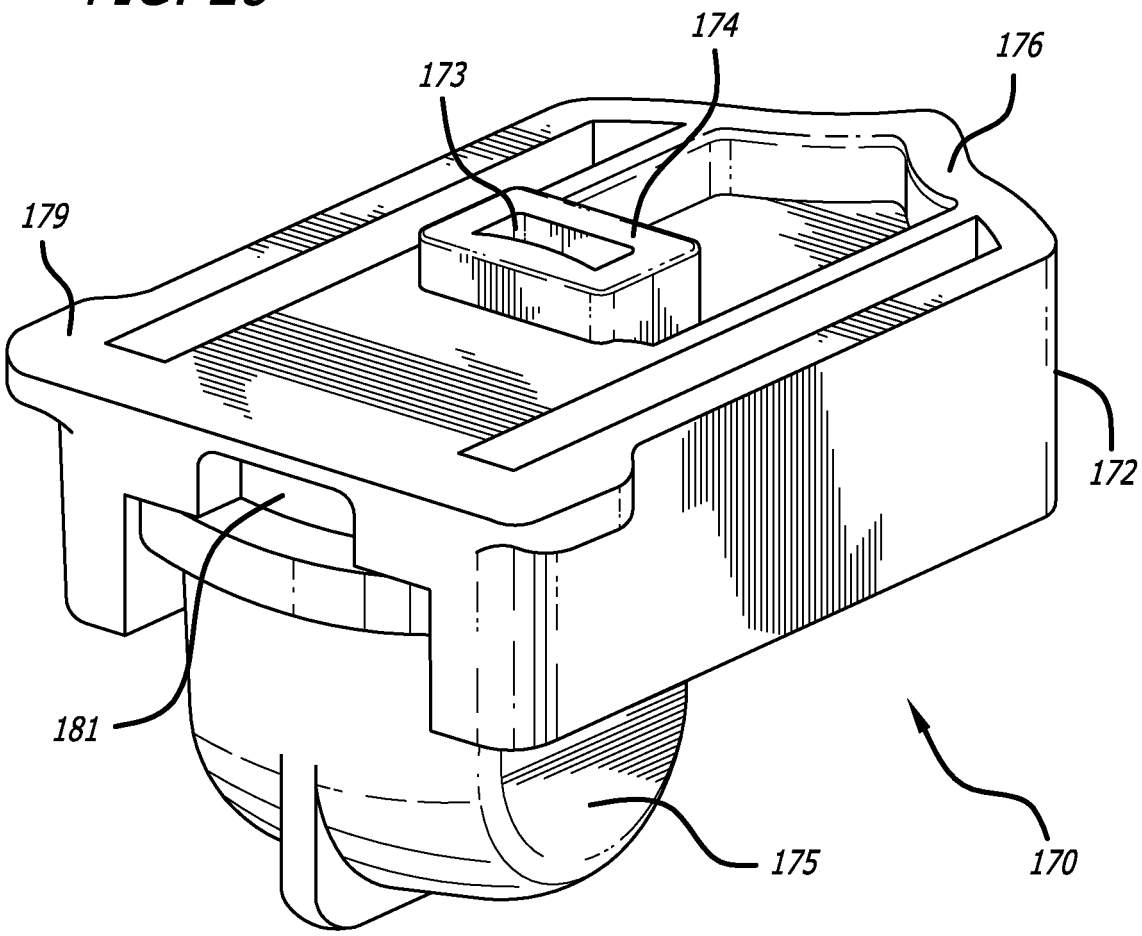


FIG. 29

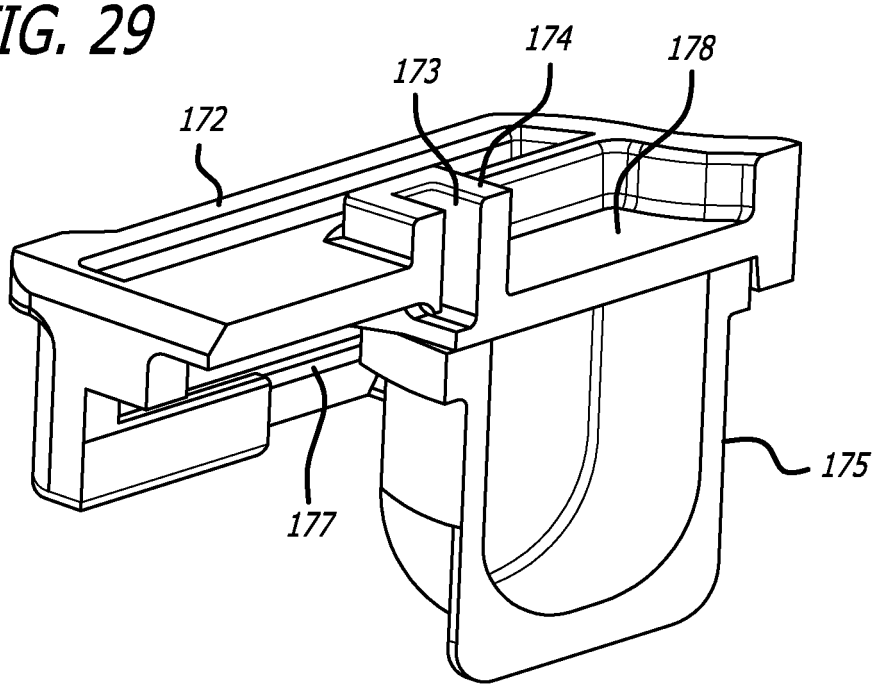
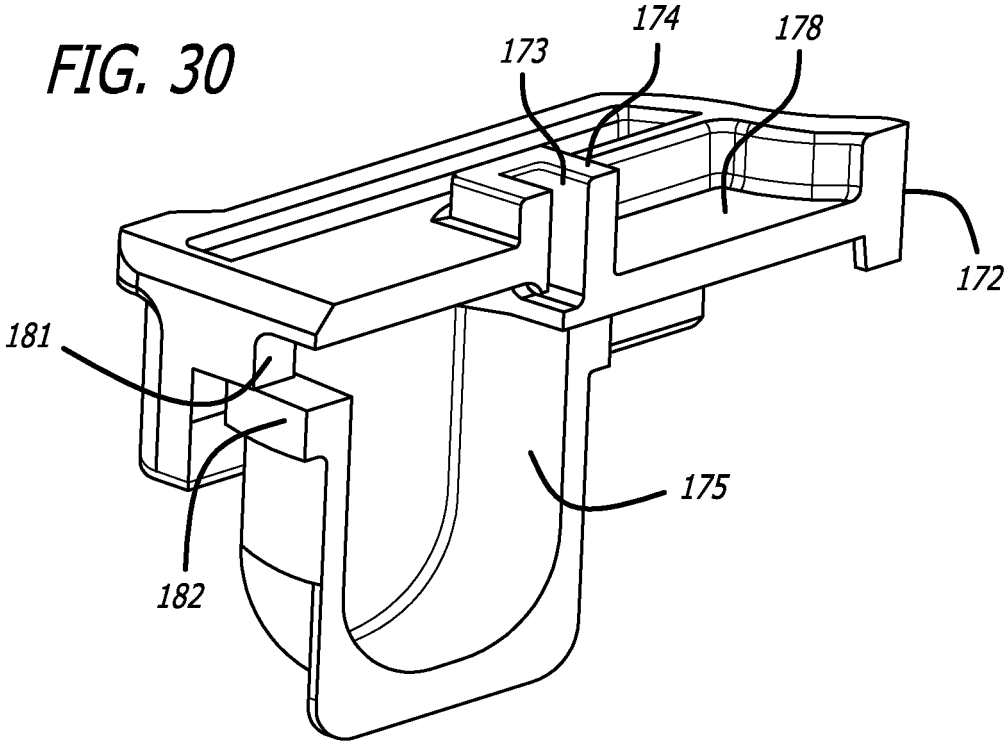


FIG. 30



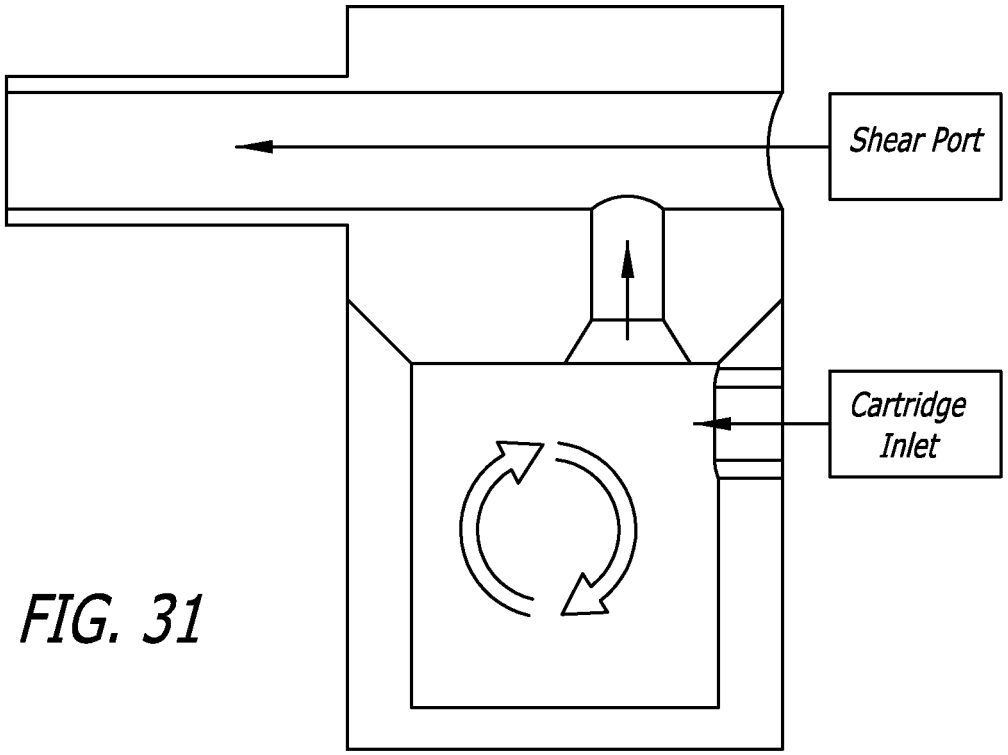

Shear Port
Cartridge Inlet

FIG. 31

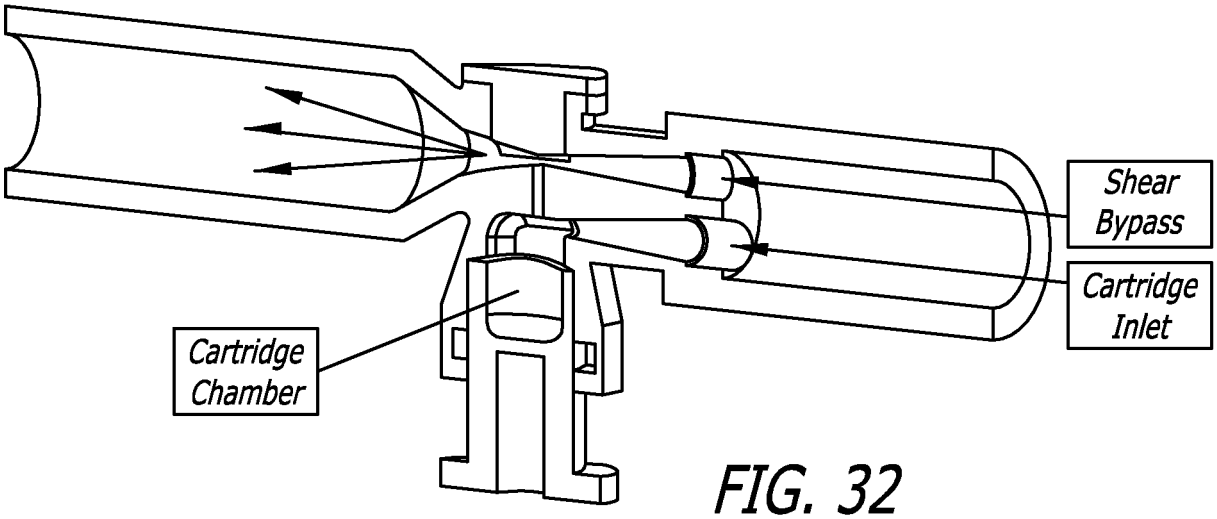
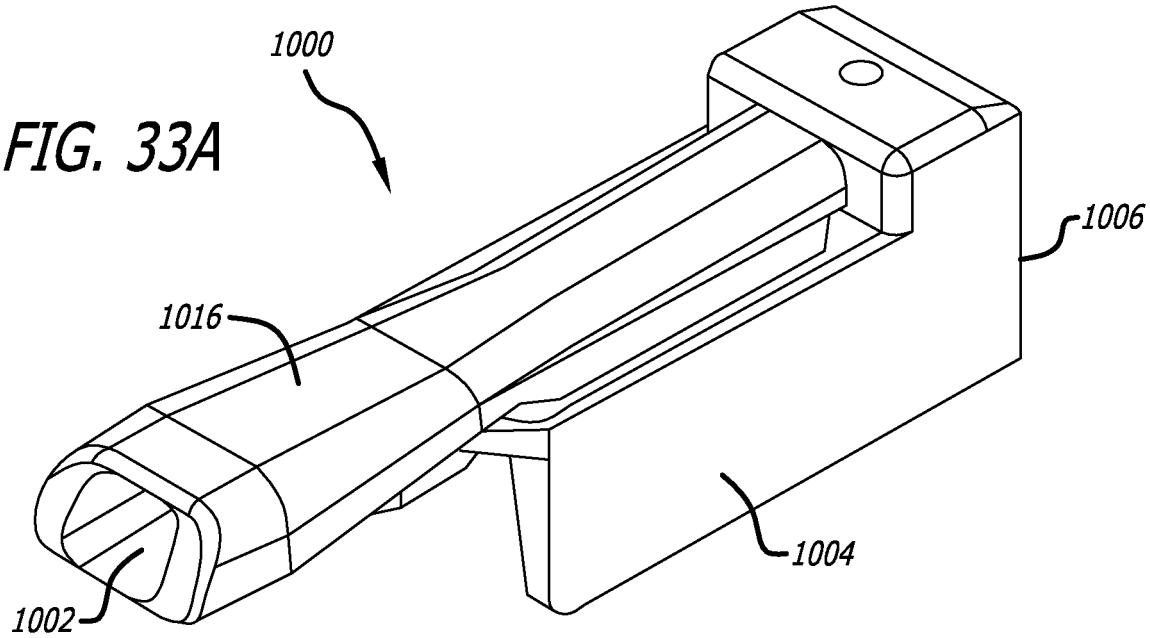

Shear Bypass
Cartridge Inlet
Cartridge Chamber

FIG. 32

FIG. 33A



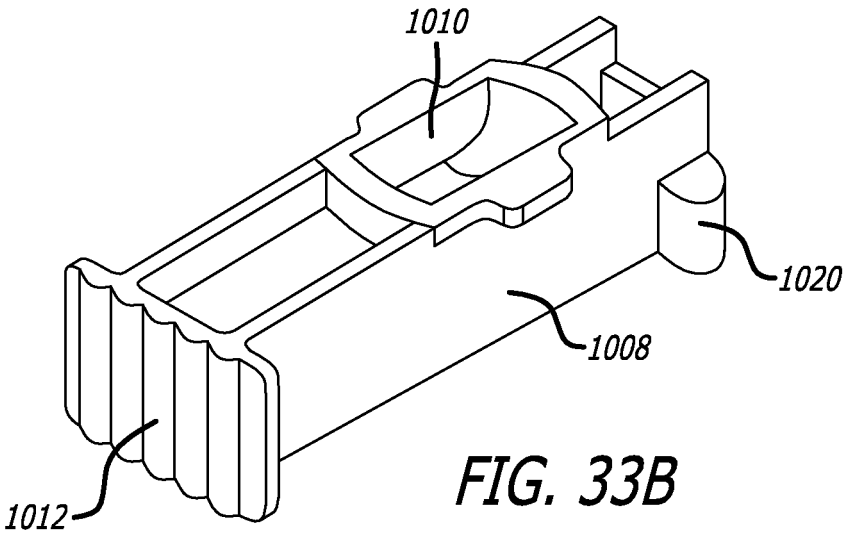


FIG. 33B

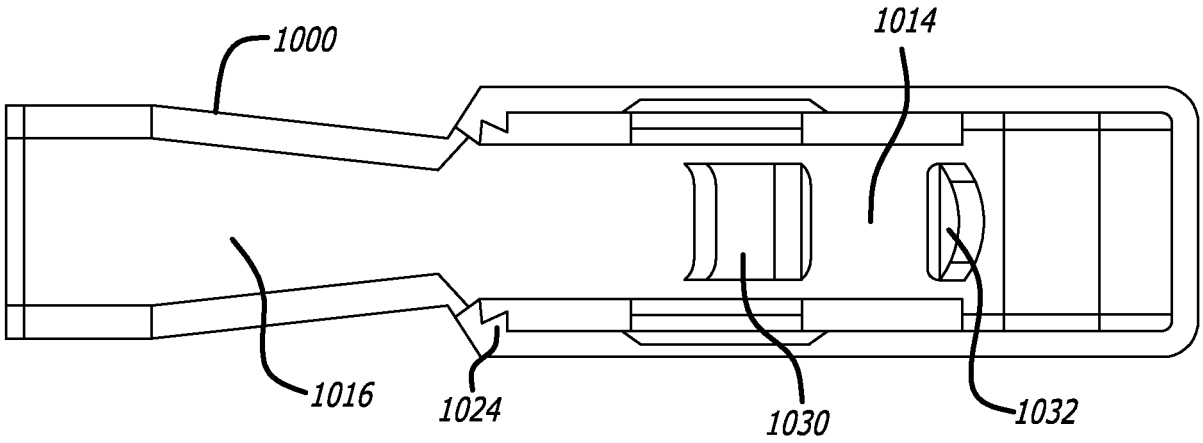


FIG. 33C

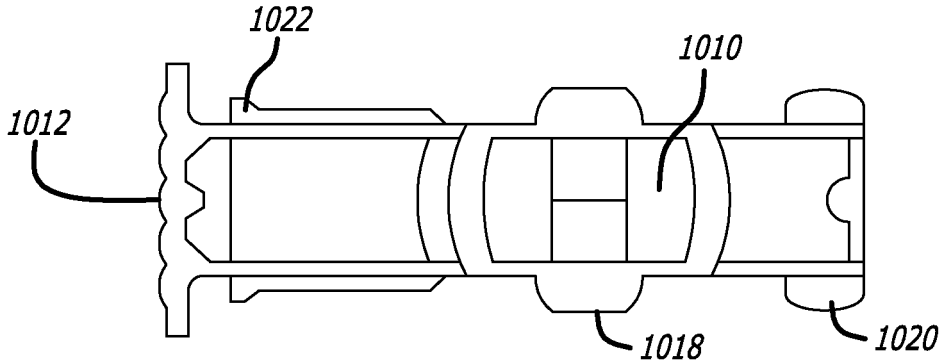


FIG. 33D

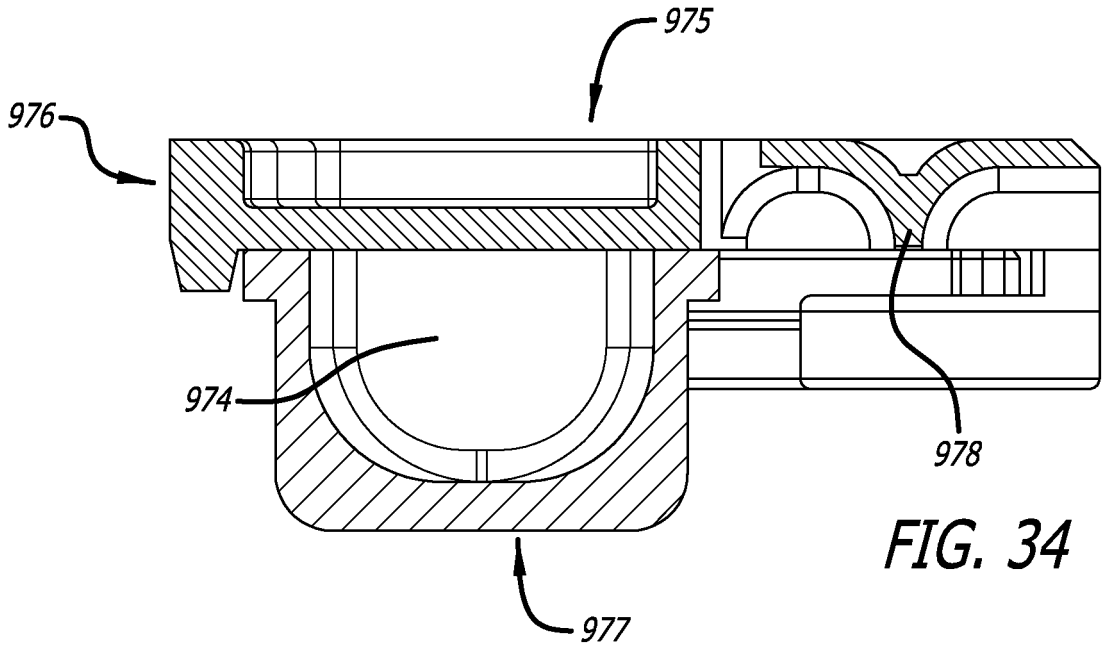


FIG. 34

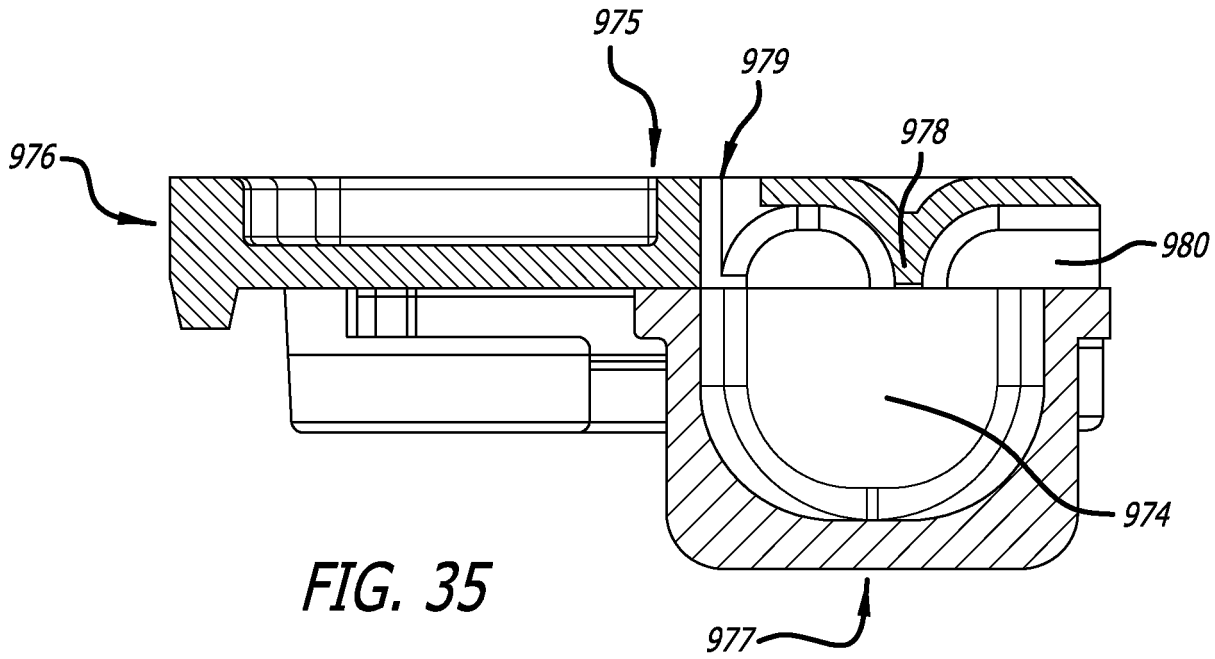


FIG. 35

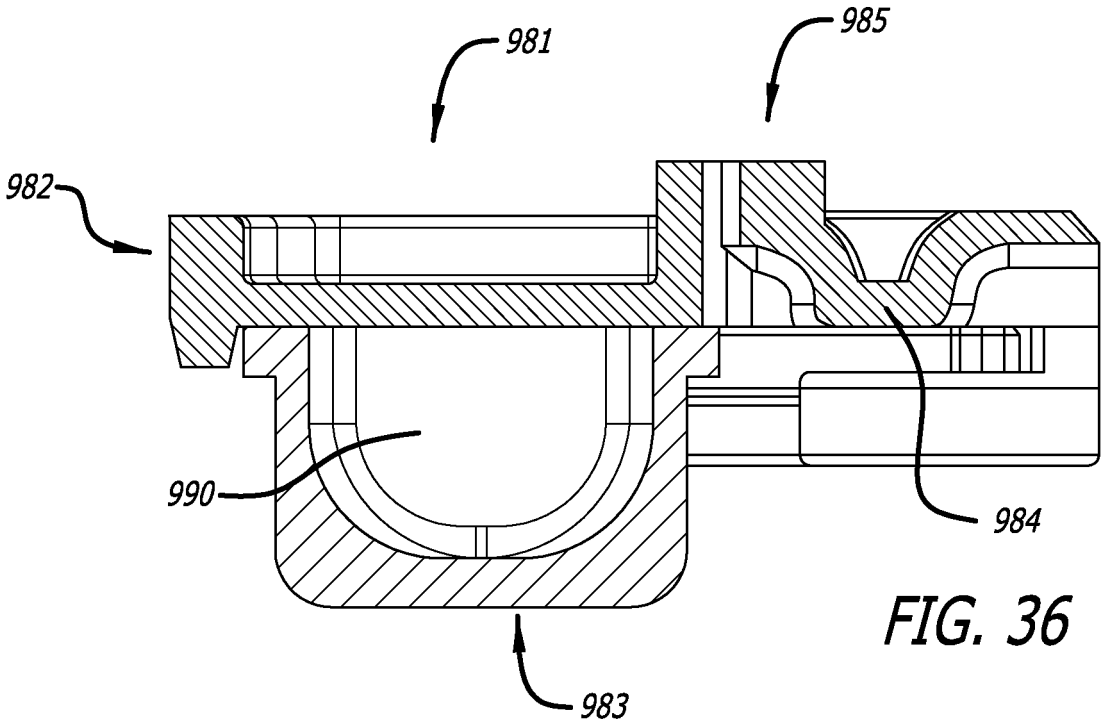


FIG. 36

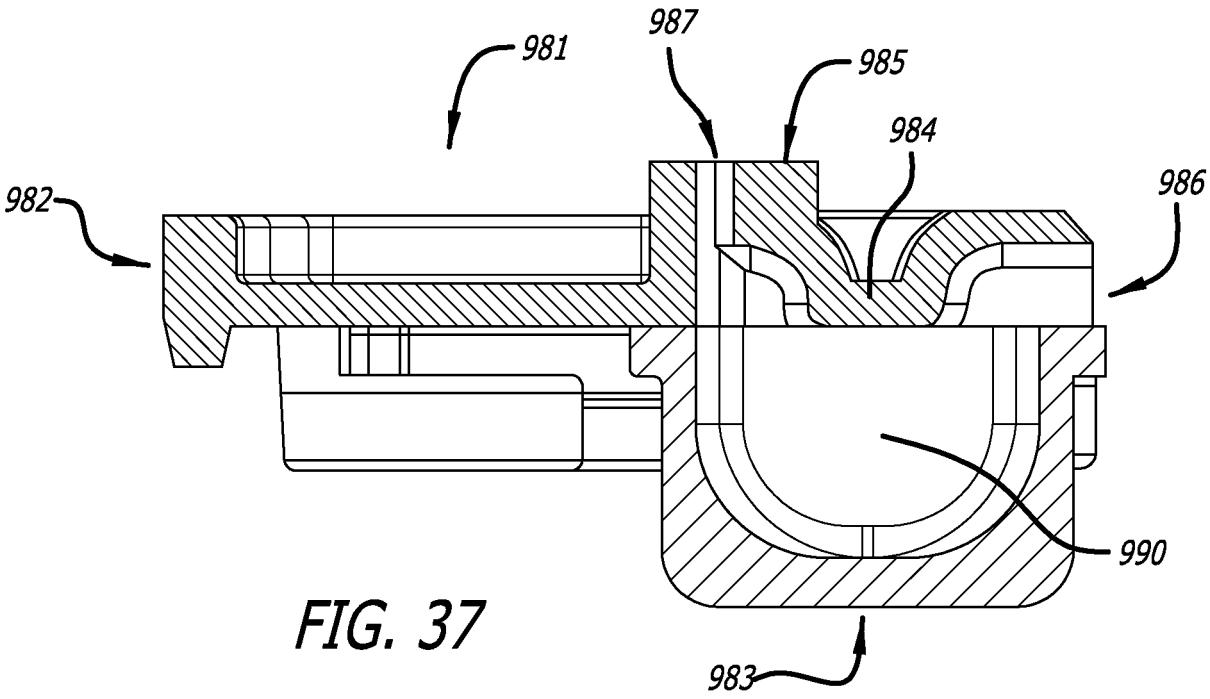


FIG. 37

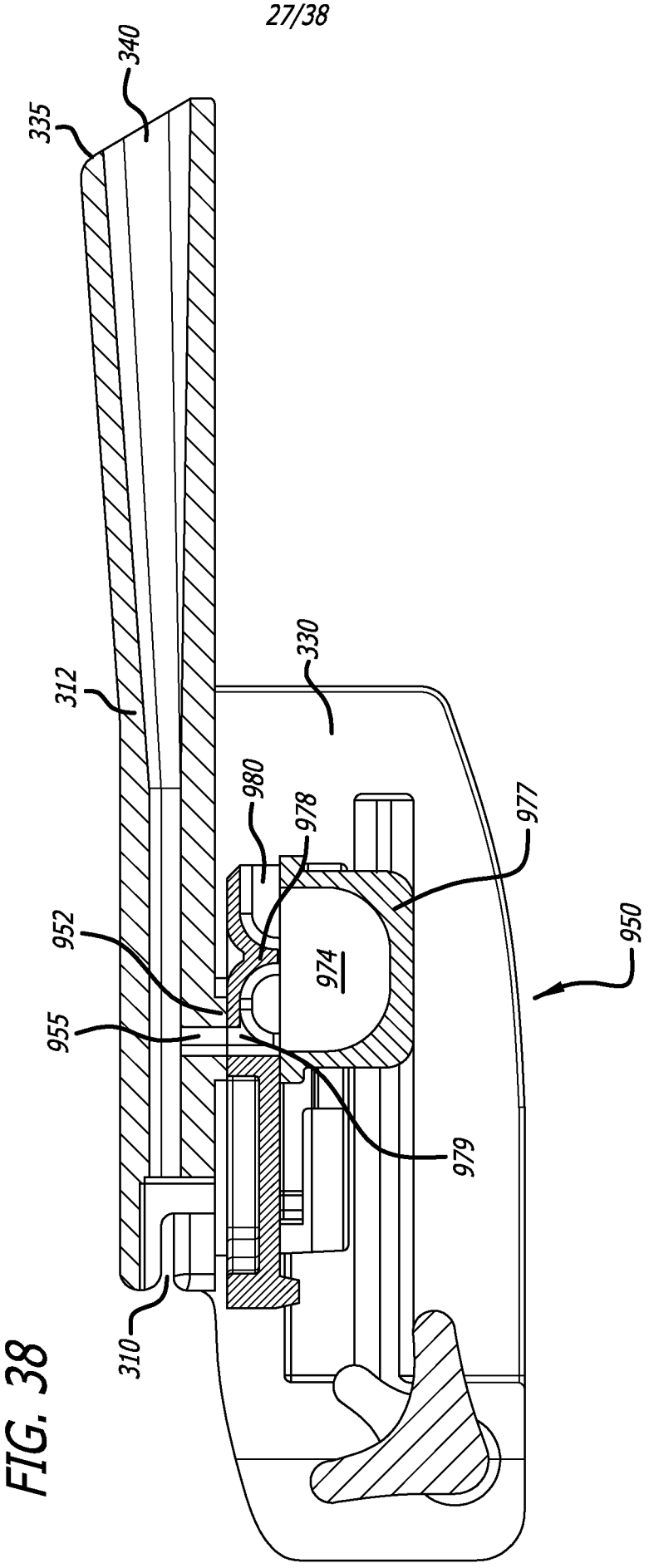


FIG. 38

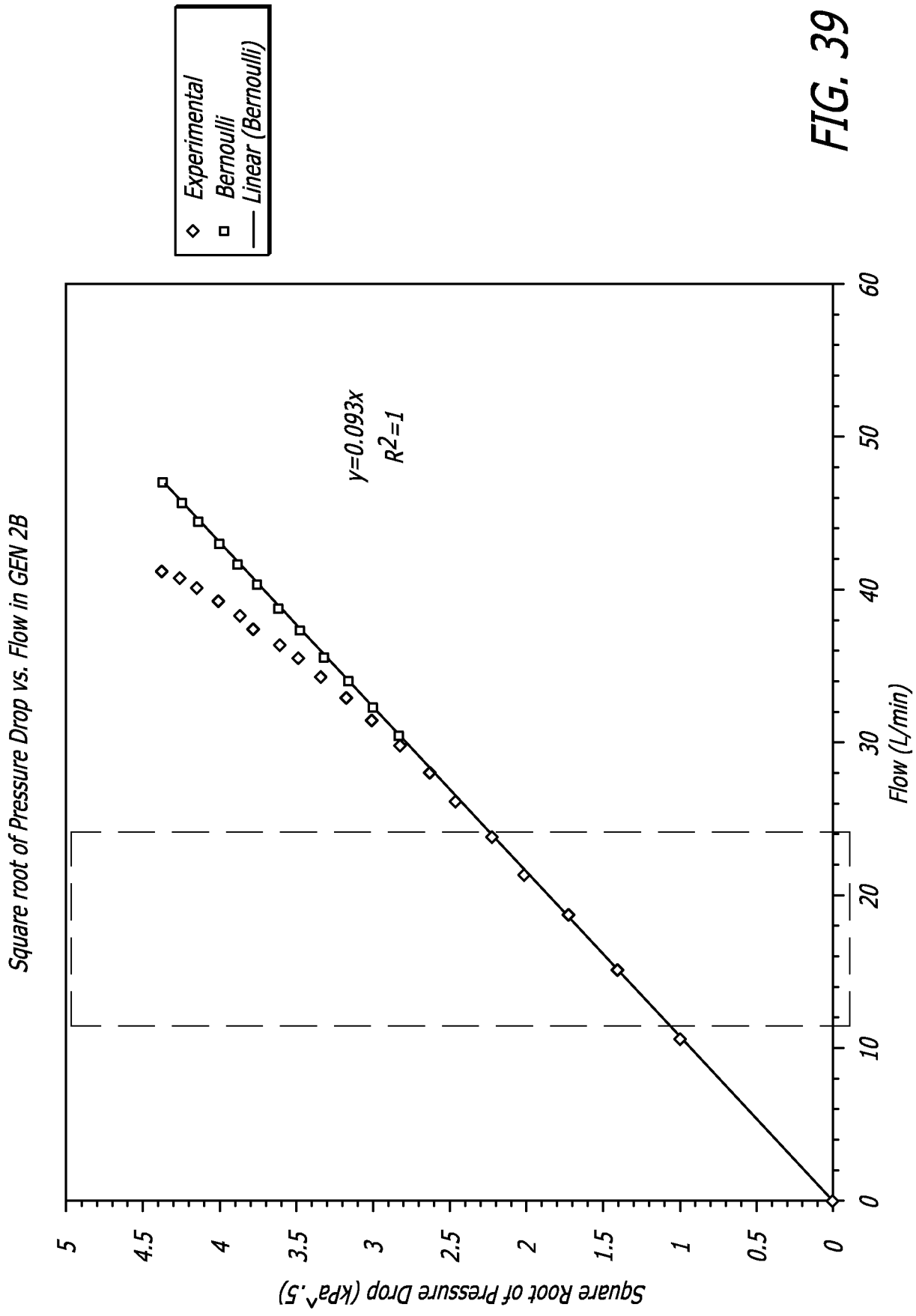

Square root of Pressure Drop vs. Flow in GEN 2B
Experimental
Bernoulli
Linear (Bernoulli)
y=0.093x
R2=1
Square Root of Pressure Drop (kPa^.5)
Flow (L/min)
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
0
10
20
30
40
50
60

FIG. 39

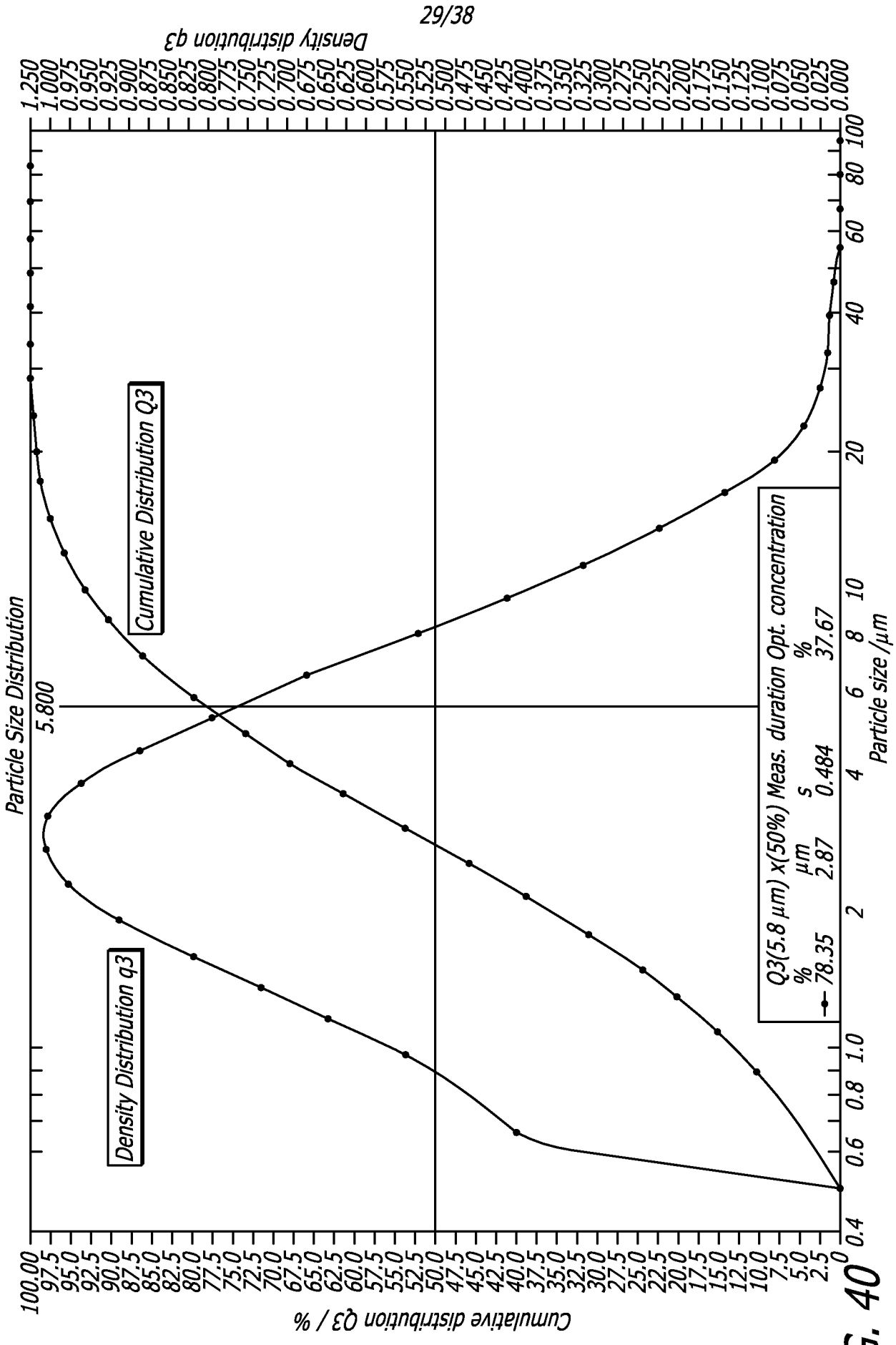

Particle Size Distribution
Cumulative Distribution Q3
Density Distribution q3
Cumulative distribution Q3 / %
Density distribution q3
Particle size /µm
5.800
Q3(5.8 µm) x(50%) Meas. duration Opt. concentration
% µm s %
78.35 2.87 0.484 37.67

FIG. 40

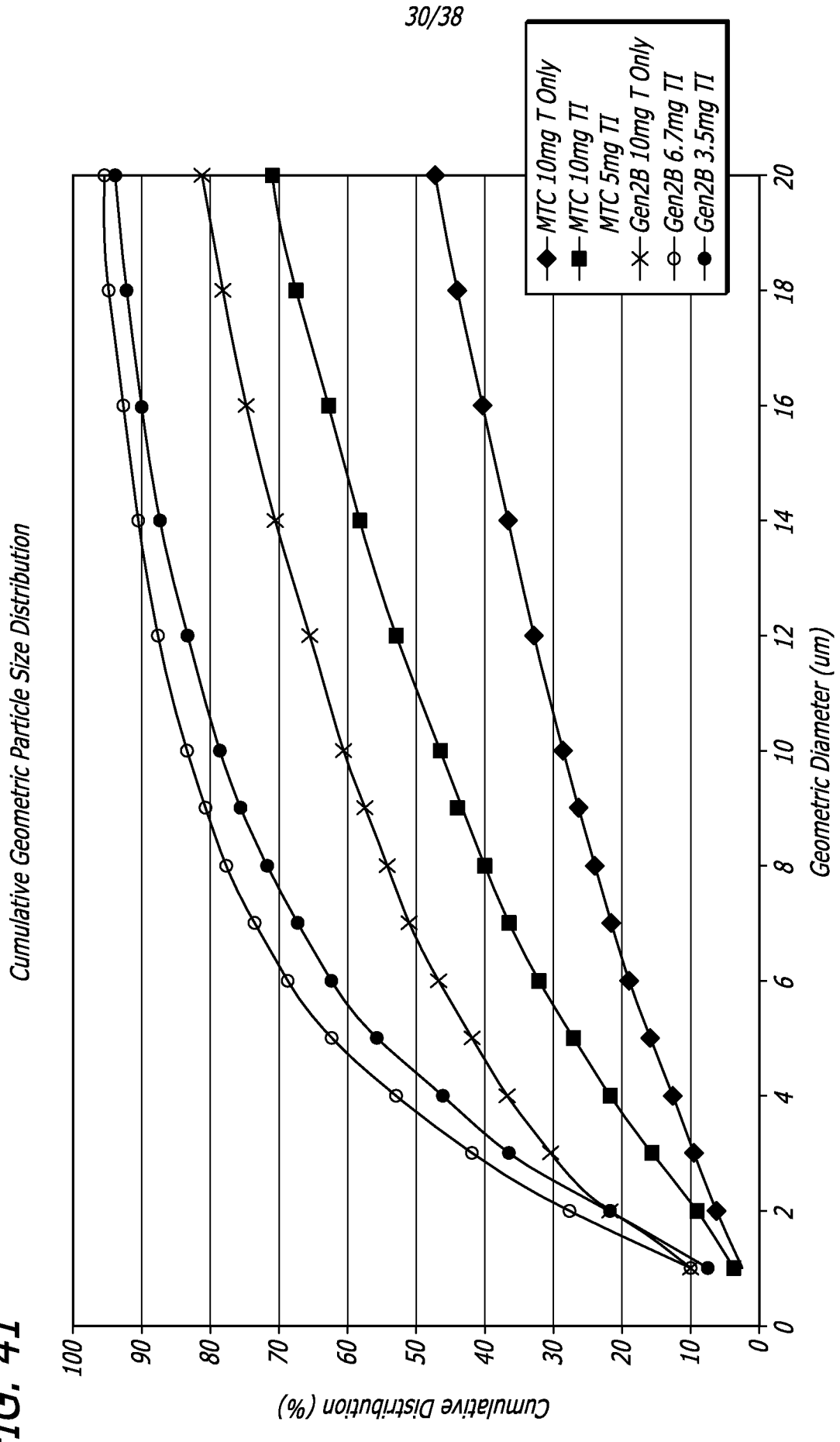

Cumulative Geometric Particle Size Distribution
Cumulative Distribution (%)
Geometric Diameter (um)
MTC 10mg T Only
MTC 10mg TI
MTC 5mg TI
Gen2B 10mg T Only
Gen2B 6.7mg TI
Gen2B 3.5mg TI
0
10
20
30
40
50
60
70
80
90
100
0
2
4
6
8
10
12
14
16
18
20

FIG. 41

FIG. 42

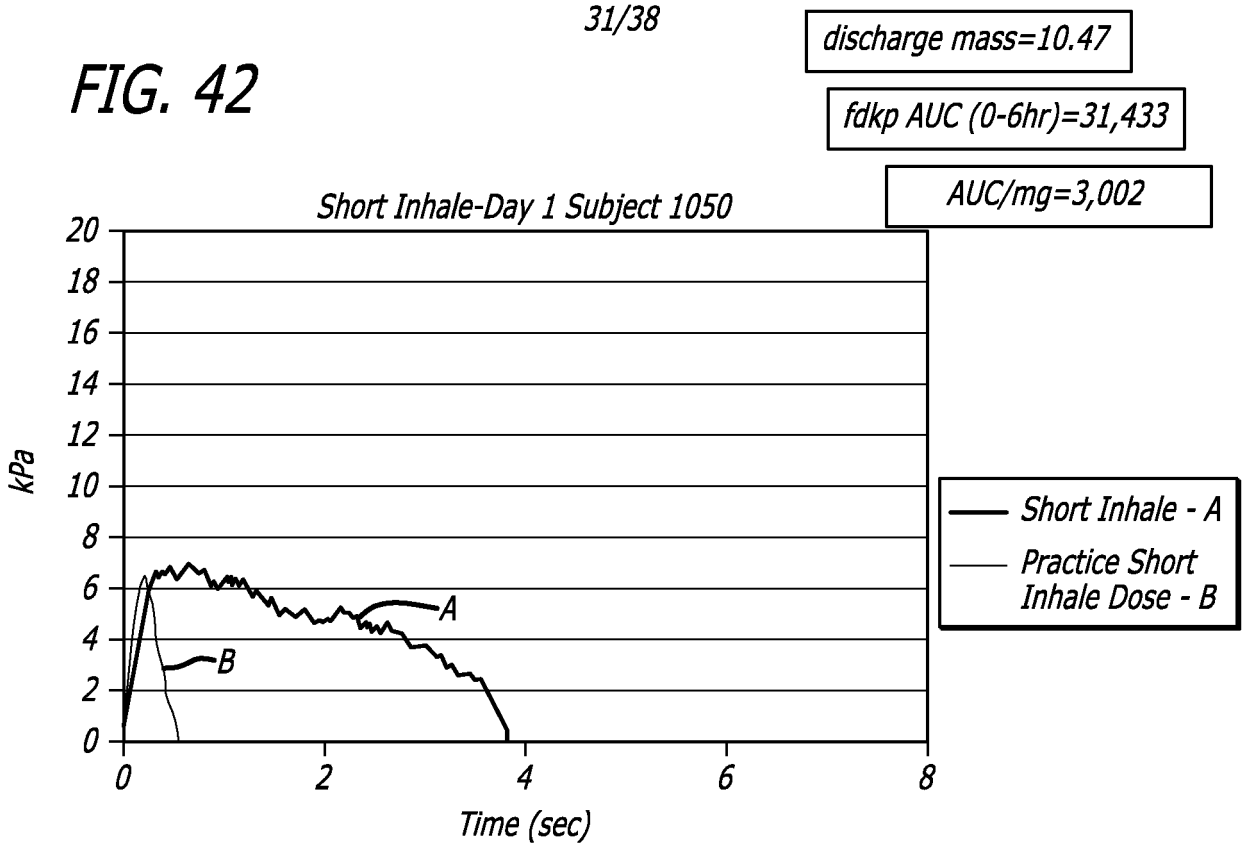

discharge mass=10.47
fdkp AUC (0-6hr)=31,433
AUC/mg=3,002
Short Inhale-Day 1 Subject 1050
kPa
20
18
16
14
12
10
8
6
4
2
0
0
2
4
6
8
Time (sec)
A
B
Short Inhale - A
Practice Short Inhale Dose - B

FIG. 43

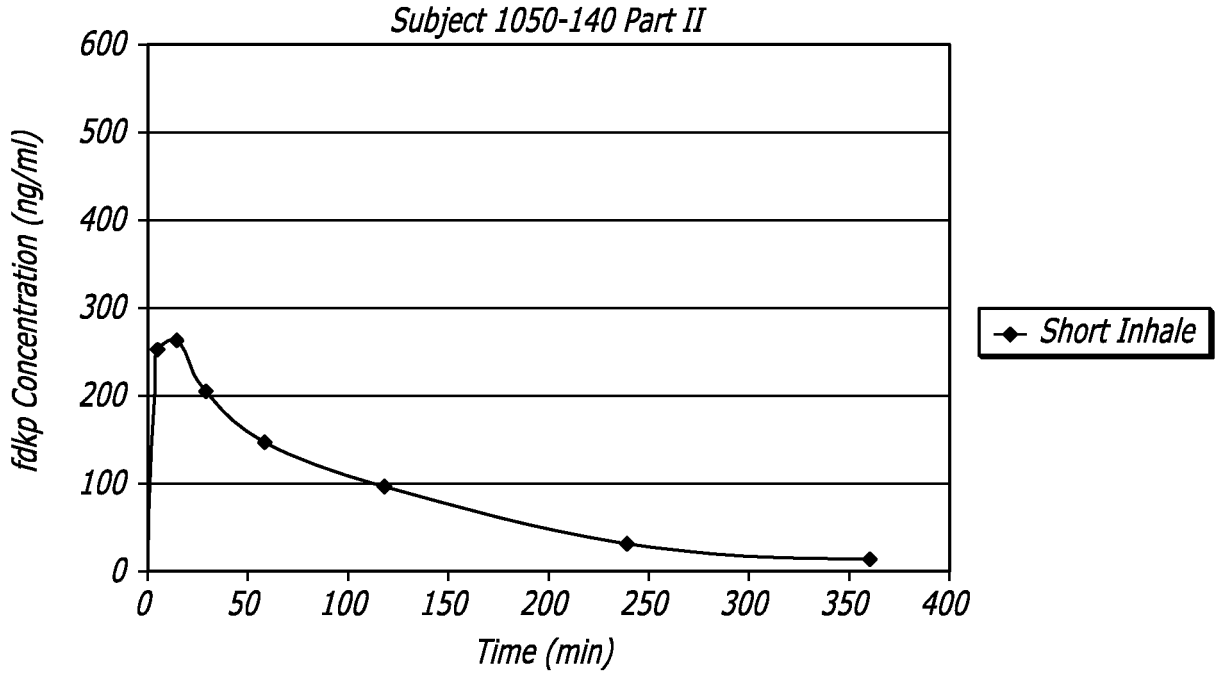
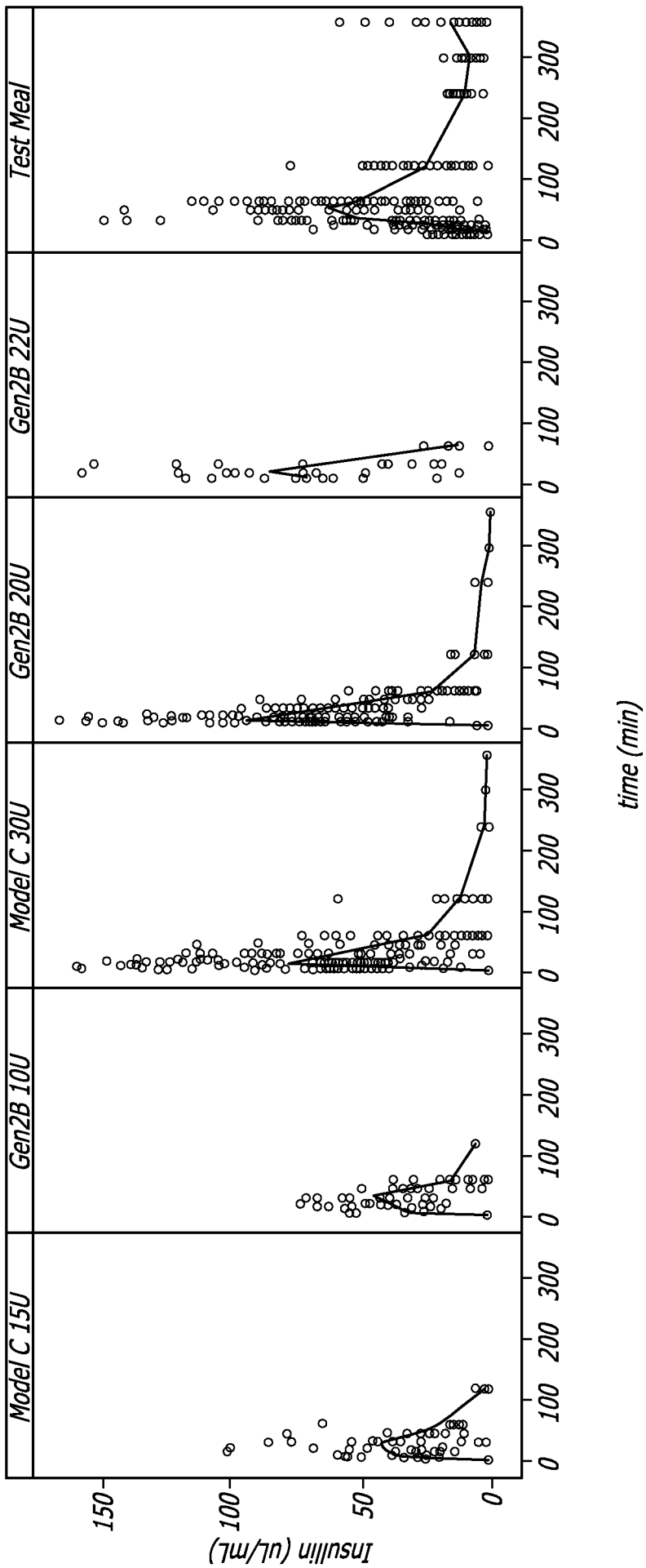

Subject 1050-140 Part II
fdkp Concentration (ng/ml)
600
500
400
300
200
100
0
0
50
100
150
200
250
300
350
400
Time (min)
Short Inhale

FIG. 44


Model C 15U
Gen2B 10U
Model C 30U
Gen2B 20U
Gen2B 22U
Test Meal
Insulin (uL/mL)
150
100
50
0
0
100
200
300
time (min)

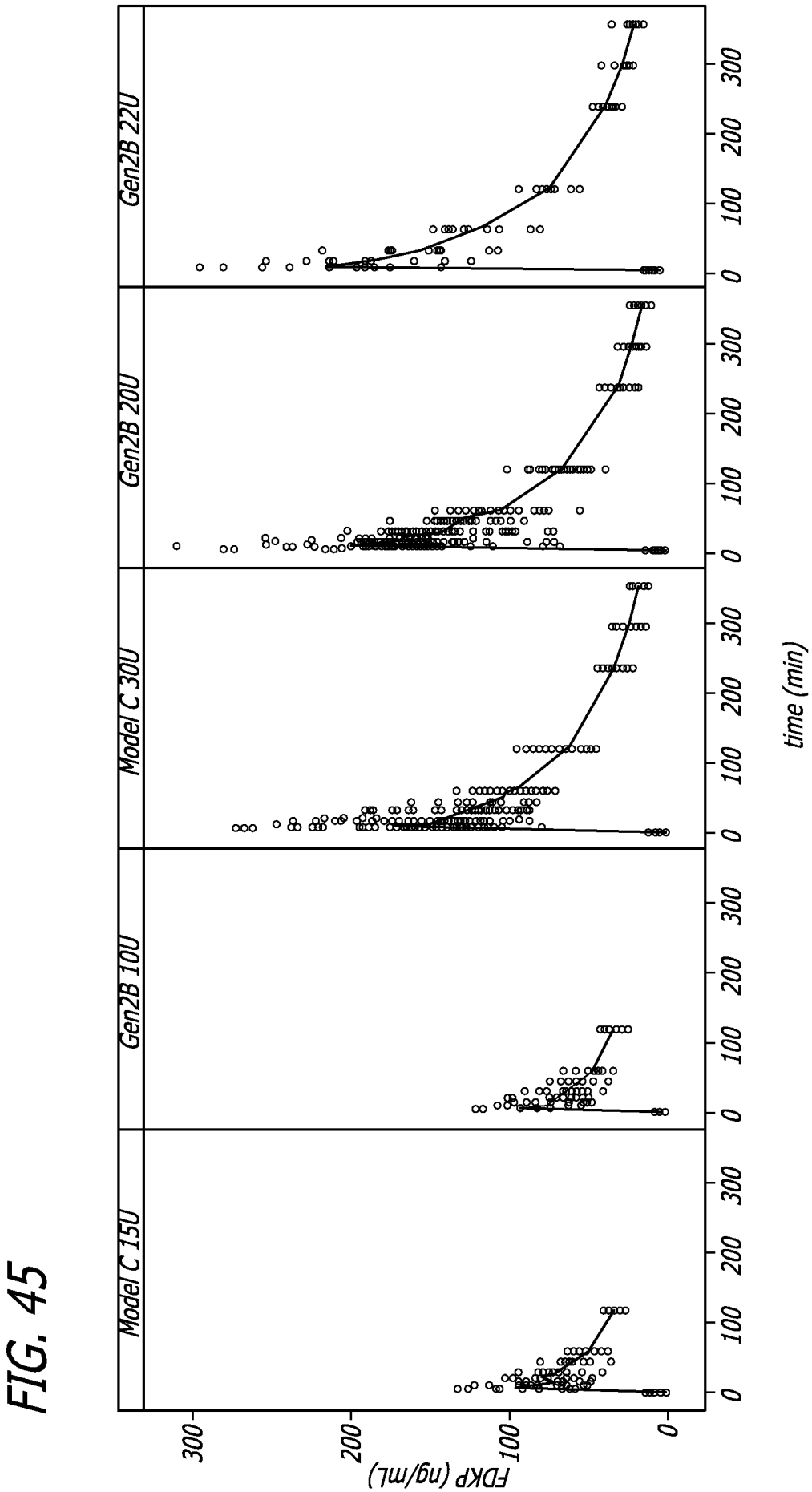

Model C 15U
Gen2B 10U
Model C 30U
Gen2B 20U
Gen2B 22U
FDKP (ng/mL)
0
100
200
300
time (min)
0
100
200
300

FIG. 45

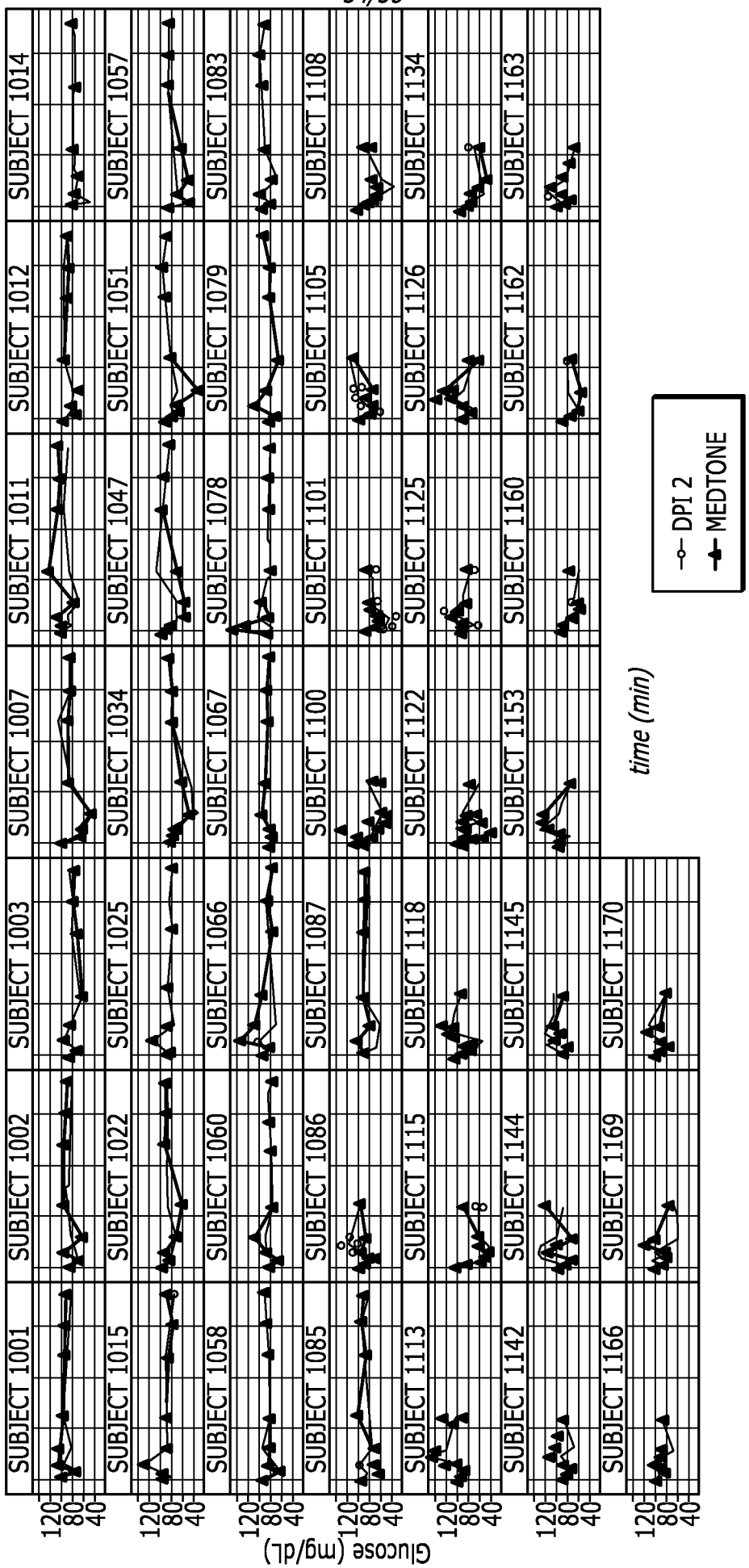

SUBJECT 1001
SUBJECT 1002
SUBJECT 1003
SUBJECT 1007
SUBJECT 1011
SUBJECT 1012
SUBJECT 1014
SUBJECT 1015
SUBJECT 1022
SUBJECT 1025
SUBJECT 1034
SUBJECT 1047
SUBJECT 1051
SUBJECT 1057
SUBJECT 1058
SUBJECT 1060
SUBJECT 1066
SUBJECT 1067
SUBJECT 1078
SUBJECT 1079
SUBJECT 1083
SUBJECT 1085
SUBJECT 1086
SUBJECT 1087
SUBJECT 1100
SUBJECT 1101
SUBJECT 1105
SUBJECT 1108
SUBJECT 1113
SUBJECT 1115
SUBJECT 1118
SUBJECT 1122
SUBJECT 1125
SUBJECT 1126
SUBJECT 1134
SUBJECT 1142
SUBJECT 1144
SUBJECT 1145
SUBJECT 1153
SUBJECT 1160
SUBJECT 1162
SUBJECT 1163
SUBJECT 1166
SUBJECT 1169
SUBJECT 1170
120
80
40
Glucose (mg/dL)
time (min)
DPI 2
MEDTONE

FIG. 46

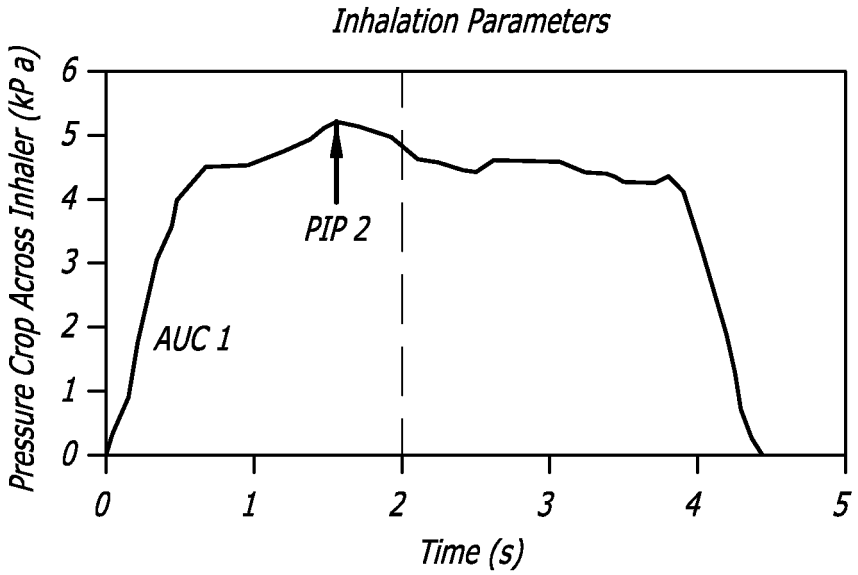

Inhalation Parameters
Pressure Crop Across Inhaler (kP a)
6
5
4
3
2
1
0
PIP 2
AUC 1
0
1
2
3
4
5
Time (s)

FIG. 47

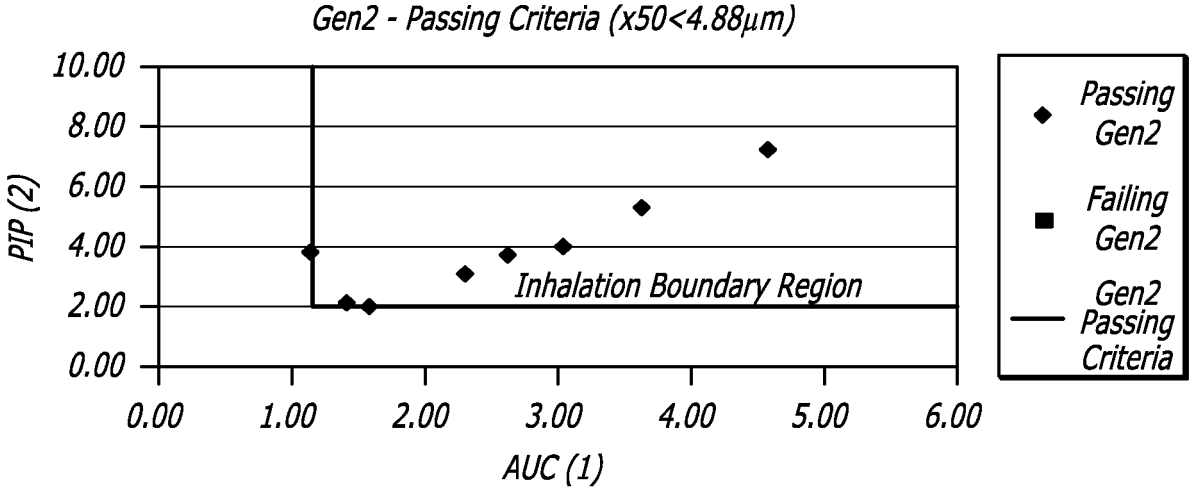

Gen2 - Passing Criteria (x50<4.88µm)
PIP (2)
10.00
8.00
6.00
4.00
2.00
0.00
Inhalation Boundary Region
0.00
1.00
2.00
3.00
4.00
5.00
6.00
AUC (1)
Passing Gen2
Failing Gen2
Gen2 Passing Criteria

FIG. 48

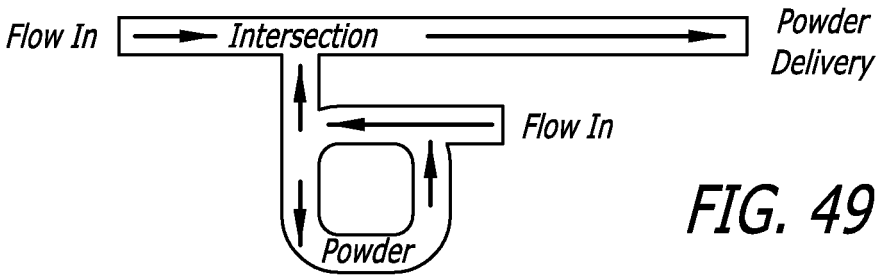


FIG. 49

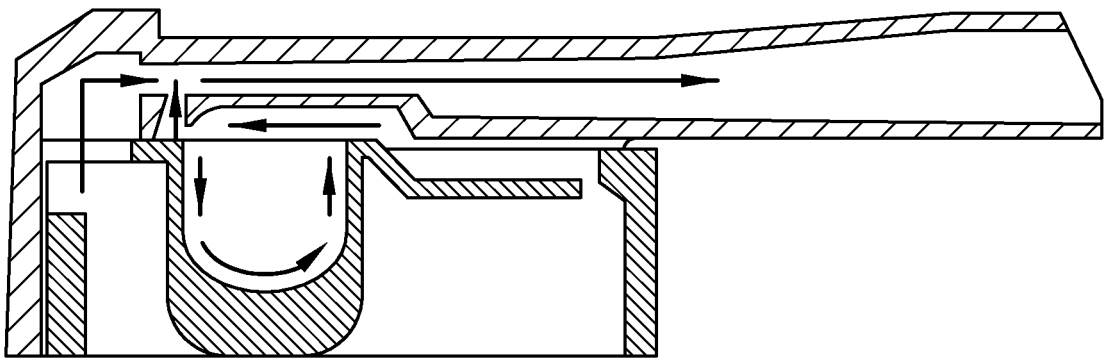


FIG. 50

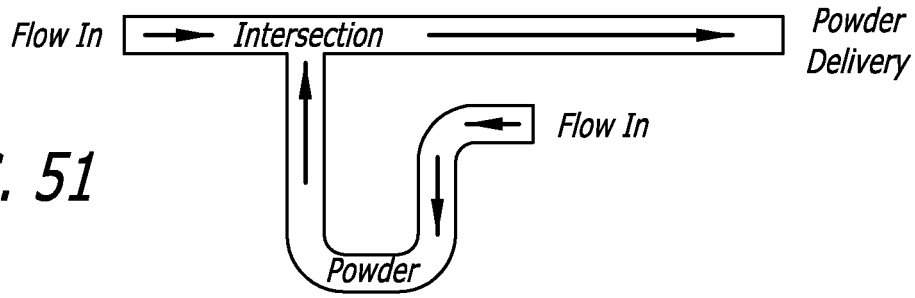


FIG. 51

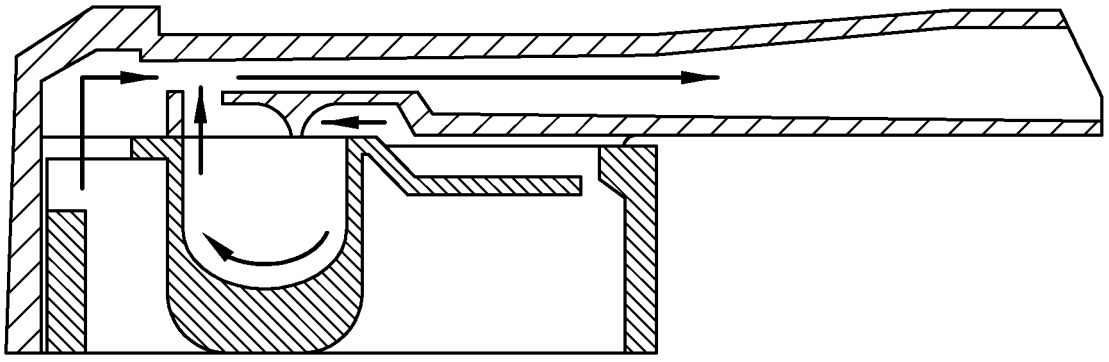


FIG. 52

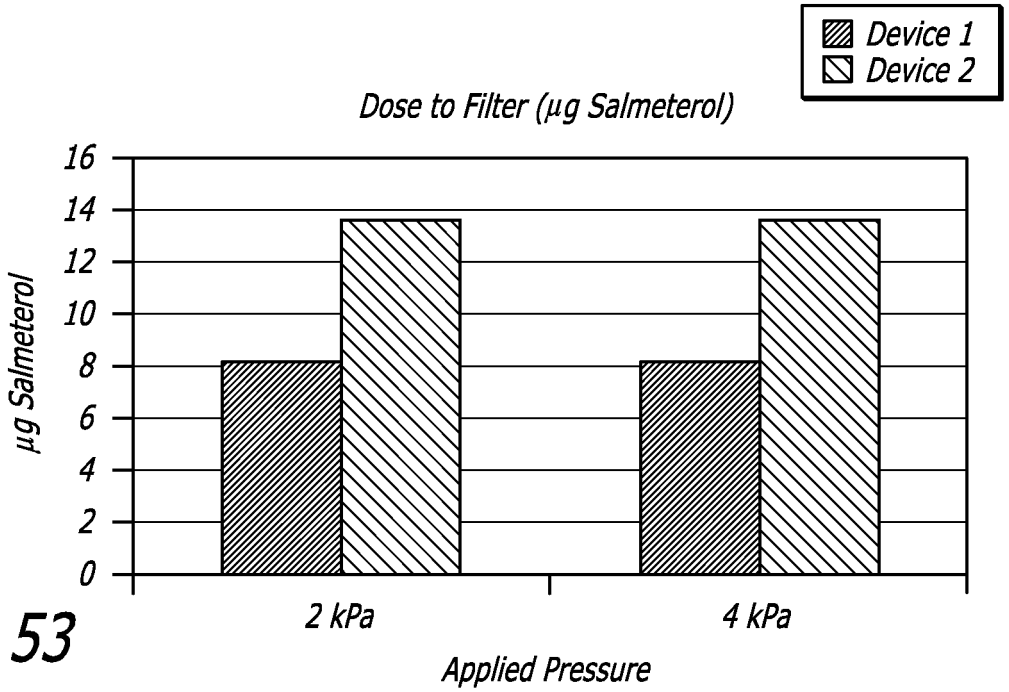

Device 1
Device 2
Dose to Filter (µg Salmeterol)
µg Salmeterol
16
14
12
10
8
6
4
2
0
2 kPa
4 kPa
Applied Pressure

FIG. 53

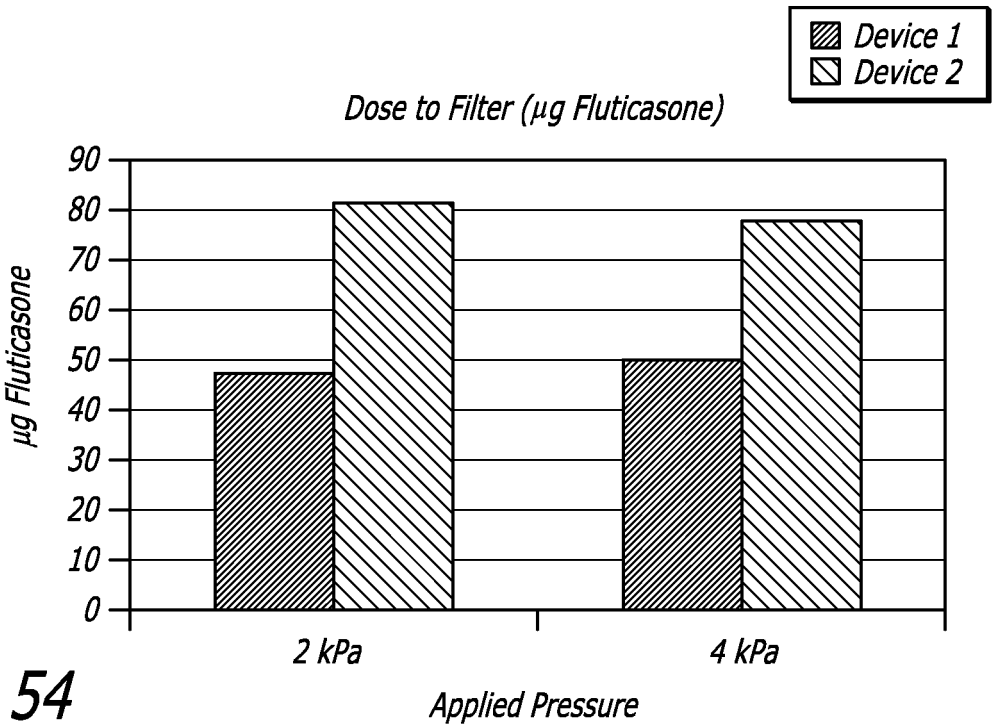

Device 1
Device 2
Dose to Filter (µg Fluticasone)
µg Fluticasone
90
80
70
60
50
40
30
20
10
0
2 kPa
4 kPa
Applied Pressure

FIG. 54