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12/426,175	04/17/2009	Jeremy B. Cox	101672.0074P2	4292
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Rutan & Tucker, LLP 611 ANTON BLVD SUITE 1400 COSTA MESA, CA 92626			D ABREU, MICHAEL JOSEPH	
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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* JEREMY B. COX,  
ANTHONY K. MISENER, CATHERINE C. BREITER,  
BRET HAMATAKE, EDDIE K. BURNSIDE,  
JASON R. STATS, and AMIR OROME

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Appeal 2015-002492  
Application 12/426,175  
Technology Center 3700

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Before JAMES P. CALVE, GEORGE R. HOSKINS, and  
ARTHUR M. PESLAK, *Administrative Patent Judges*.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the final rejection of claims 1–21. Appeal Br. 4. We have jurisdiction under 35 U.S.C. § 6(b).  
We REVERSE.

### CLAIMED SUBJECT MATTER

Claim 1, the sole independent claim, is reproduced below.

1. A medical device placement system, comprising:  
a medical device assembly including a medical device for placement within a body of a patient and a sensing component, the medical device assembly at least partially disposed in a sterile field, a first connector operably connected to the sensing component including a first contact;  
a data-receiving component at least partially disposed in a non-sterile field, a second connector operably connected to the data-receiving component including a second contact; and  
means for establishing a conductive pathway between the sterile field and the non-sterile field after the sterile field has been established by creating a perforation in a drape separating the sterile field and the non-sterile field with either the first connector or second connector so as to operably connect the sensing component to the data-receiving component without compromising the sterile field.

### REJECTION

Claims 1–21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Goldin (US 6,546,270 B1, iss. Apr. 8, 2003), and either of Mackey (US 5,423,877, iss. June 13, 1995) or Pyles (US 2005/0283216 A1, pub. Dec. 22, 2005).

### ANALYSIS

*Claims 1–21 as unpatentable over Goldin and either Mackey or Pyles*

The Examiner interpreted the “means for establishing a conductive pathway” in claim 1 as invoking 35 U.S.C. § 112, sixth paragraph. Final Act. 2. The Examiner found that Appellants disclose connector schemes as structures to that claimed function. *Id.* at 3.

The Examiner found that Goldin teaches a medical device assembly with catheter 20, sensing component (location sensor 28), a first conductor/connector (wire 54) extending the length of the device to contact pin 40, and a second connector (wire 52) connected to a data-receiving component. *Id.* at 5. The Examiner also found that the first connector (wire 54 in Figure 3) corresponds to the means for establishing a conductive pathway between the sterile and the non-sterile fields. *Id.*; *see* Ans. 3.

The Examiner found that Golden does not teach creating a perforation in a drape that separates sterile and non-sterile fields, but Mackey and Pyles teach the use of sterile drapes at an insertion site for insertion of a catheter into a patient. Final Act. 6. The Examiner determined that it would have been obvious to use a sterile drape as taught by Mackey or Pyles and to establish a conductive pathway between an internal sterile field of a patient and a non-sterile field outside the patient by perforating the drape. *Id.*

Appellants argue that Goldin does not disclose a medical device with a drape to define a sterile barrier and even if the sterile field is limited to the patient's body, Goldin's catheter body traverses this boundary and Goldin does not provide any connector along the catheter body in any area at or near the patient boundary. Appeal Br. 13–14. Appellants argue that they define a sterile field in their Specification as

A sterile drape that is positioned over the patient 70 during the catheter insertion procedure defines the majority of the sterile field: areas above the drape are sterile, while areas below (excluding the insertion site and immediately surrounding region) are non-sterile.

*Id.* at 14 (quoting Spec. ¶ 84 with emphasis added by Appellants).

Appellants also argue that Mackey does not disclose any perforation in a drape and Pyles discloses a sterile drape having an opening therein for access to a site to be punctured, but neither reference teaches means to form a perforation in a drape with a first or second connector. Appeal Br. 15–16. Appellants further argue that elements 52 and 54 in Figure 3 of Goldin run the entire length of the device and do not cause any perforation of a drape as they are housed in the body of catheter 20. *Id.* at 16–17. We agree.

The Examiner has not established by a preponderance of evidence that wires 52, 54 of Goldin provide a structure corresponding to the “means for establishing a conductive pathway . . . by creating a perforation in a drape separating the sterile field and the non-sterile field.” Appellants disclose tether connector 132 with pin contact 170 that pierces drape 174 when tether connector 132 connects to fin connector 156 and establishes a conductive pathway with fin contact 168 as shown in Figure 15 below.

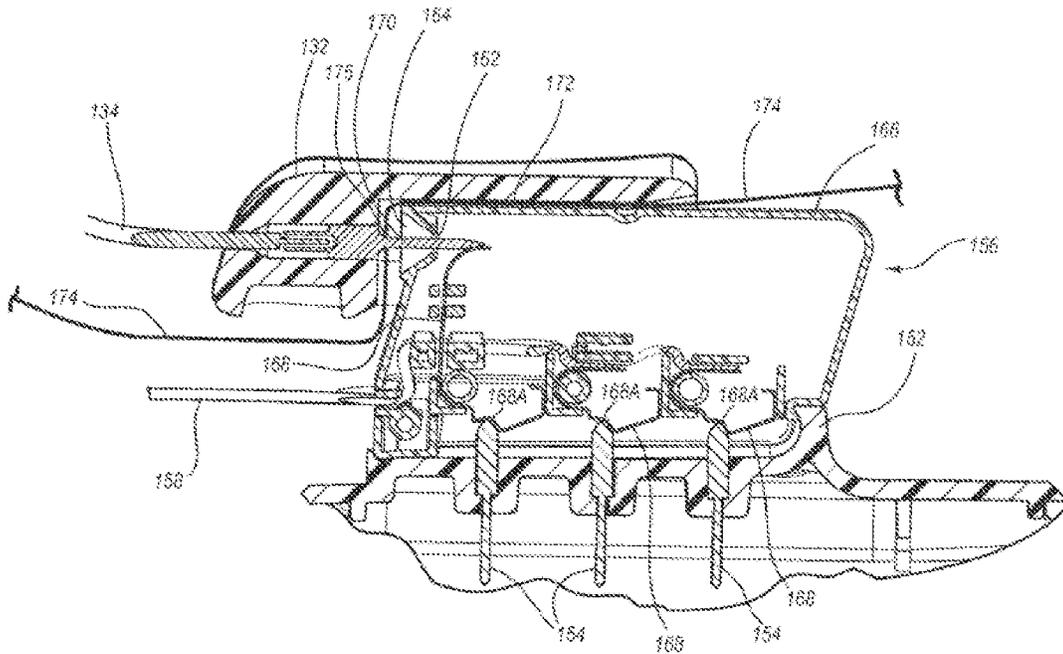


FIG. 15

Figure 15 of Appellants' disclosure is a cross-section of stylet tether, fin connector, and tip location/navigation (TLS) sensor 50 with drape 174. Pin contact 170 forms perforation 175 in drape 174 and passes through centering hole 164 to contact fin contact 168. Spec. ¶ 93. Pin contact 170 forms and occupies a small perforation 175, thus minimizing the size of the perforation in sterile drape 174. Tether connector channel 172 encloses the perforation 175 to preserve the sterility of drape 174. *Id.*

The Examiner's finding that Pyles creates a perforation in a drape by disclosing a drape with an opening for access to an insertion site (Pyles ¶ 24) does not explain how Goldin's wire 54, which the Examiner finds is the first connector and the claimed "means" (Final Act. 5), creates a perforation in a drape as claimed. Ans. 5. Wires 52, 54 extend from reference electrode 25 and location sensor 28, respectively, near catheter tip 26 and inside a body of catheter 20 to catheter handle 30 and then via electrical connections to signal processing circuits 40. Goldin, 12:28–32, Figs. 1, 3. Even if wires 52, 54 are considered to be connectors, they do not provide structure or equivalent structure to create a perforation in a drape, as the Examiner admits. Ans. 6. The Examiner's interpretation of the "means" in claim 1 as not requiring structure to perforate a drape (*id.*) is not consistent with the plain language of claim 1 interpreted in light of Appellants' Specification.

We do not sustain the rejection of claims 1–21.

#### DECISION

We reverse the rejection of claims 1–21.

REVERSED