

ENCISION INC
Form 8-K
April 13, 2004

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of Earliest event reported): April 8, 2004.

ENCISION, INC.

(Exact name of Registrant as specified in its charter)

Colorado
(State or other jurisdiction
of incorporation)

0-28604
(Commission
File Number)

84-1162056
(IRS Employer
Identification No.)

4828 Sterling Dr., Boulder, Colorado
(Address of principal executive offices)

80301
(Zip Code)

Registrant's telephone number, including area code **(303) 444-2600**

Item 9. Regulation FD Disclosure.

On April 8, 2004, Encision Inc. issued a press release announcing Encision's electro-surgical technology has been cited in numerous sections in the *2004 AORN Standards, Recommended Practices and Guidelines*, published by the Association of periOperative Registered Nurses (AORN). The text of the press release is set forth beginning on the following page.

**Surgical Standards Publication Cites Encision's
Technology in New 2004 Edition**

Boulder, Colorado, April 8, 2004 Encision's (AMEX: ECI) electrosurgical technology has been cited in numerous sections in the *2004 AORN Standards, Recommended Practices and Guidelines*, published by the Association of periOperative Registered Nurses (AORN).

In the newly published 2004 Edition, the AORN includes many references to the importance of using electrosurgical devices designed for optimal safety. Included are recommendations that hospitals use surgical instruments (active electrodes) which incorporate shielding and monitoring technology to reduce the risk of inadvertent patient injury.

Recommended Practices for Endoscopic Minimally Invasive Surgery:

Electrosurgical injuries are caused by insulation failure and capacitive coupling. These should be avoided.

Perioperative team members should monitor continually the functioning and integrity of endoscopic instrumentation to ensure hazards are minimized.

Use of active electrode monitoring devices minimizes the chance of patient injury due to insulation failure and capacitive coupling.

Recommended Practices for Electrosurgery:

Personnel selecting the electrosurgical (devices) for purchase or use should make decisions based on safety features to minimize risks to patients and personnel.

Equipment selected should include technology to detect stray (electrosurgical) current that could result in patient injury.

The use of active electrode monitoring has minimized these risks.

Use of active electrode shielding and monitoring minimizes the risks of insulation failure and capacitive coupling injuries.

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Encision's AEM Surgical Instruments are shielded and monitored to prevent stray electrosurgical burn injuries to unintended tissue, a well-documented patient safety risk in minimally-invasive surgery. AEM Instruments incorporate active electrode monitoring technology to dynamically monitor the integrity of the instruments continuously during the surgical procedure, thus helping to prevent an inadvertent patient injury.

Illustrating the importance of this issue, at last week's meeting of the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), Dr. Yuri Casseres presented data on the incidence of insulation failure of endoscopic surgical instruments in a 33 hospital study. A total of 1,438 conventional laparoscopic instruments were inspected and tested. Dr. Casseres reported that:

18% of the instruments had insulation flaw(s).

Of those, 58% had insulation flaws in an area which would be outside the surgeons' field of view during the surgical procedure; hence, over 10% of all instruments in use at these hospitals are susceptible to causing stray current to unintended tissue unseen by the surgeon.

Dr. Casseres concluded, "The number of insulation defects is unacceptably high and may lead to unnecessary and easily avoidable complications." He also noted

that visual inspection of the instruments is not an adequate solution since 57% of the flawed instruments had failures which were not visible to the naked eye. The moderator of the podium presentations concurred that this is a huge problem since patient fatality is a possible outcome.

AORN is the professional organization of 41,000 perioperative personnel dedicated to achieving optimal outcomes for patients undergoing surgical procedures. As a part of their overall effort, AORN publishes *AORN Standards, Recommended Practices and Guidelines* providing guidance to perioperative personnel on what is believed to be an optimal level of practice.

AORN Recommended Practices do not endorse any specific company or product; however, Encision's AEM Instruments are the only instruments on the market which incorporate a shielded and monitored design to prevent the risk of stray electrosurgical burn injury from insulation failure and capacitive coupling in minimally invasive surgery.

Encision Inc. designs and manufactures innovative surgical devices that allow the surgeon to optimize technique and patient safety during a broad range of surgical procedures. Based in Boulder, Colorado, the Company pioneered the development of patented AEM® Laparoscopic Instruments to improve electrosurgery and reduce the chance for patient injury in minimally invasive surgery.

CONTACT:

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on our behalf by the undersigned thereunto duly authorized.

Encision Inc.

Date: April 13, 2004

/s/ Marcia K. McHaffie
Marcia K. McHaffie
Controller
Principal Accounting Officer