Nevisense

Patient Labeling

Caution: Federal law restricts this device to sale by or on the order of a physician.

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Glossary

Term	Definition
Adverse Event	An adverse event is an unwanted experience associated with the use of a medical product in a patient.
Biopsy, skin	Skin tissue that is removed and looked at under a microscope by a pathologist to check for disease.
Dermatologist	A medical doctor trained to treat skin diseases.
Electrical Impedance or Electrical Impedance Spectroscopy (EIS)	A measure of how skin resists electrical energy.
EIS score	A score from 0-10 that relates to the chance that a mole is or is not melanoma
EIS score, positive	A score from 4 – 10 that means a mole has a higher chance of being melanoma.
EIS score, negative	A score from 0 – 3 that means a mole has a low chance of being melanoma.
Melanoma	A type of skin cancer that starts in color producing cells of the skin. The most dangerous form of skin cancer.
Mole	An area of skin that looks different from the surrounding skin, It is usually pigmented (colored), and may be raised or flat.
Pathologist	Medical doctor trained to examine the tissue to check for disease.
Pivotal clinical study	A study done with patients to test the safety and effectiveness of a device or method.
Reader study, Nevisense	A study where dermatologists looked at mole images and patient information (but did not physically examine patients) to test how Nevisense information affected their ability to detect melanoma.

Purpose of the device

Nevisense is intended for use on moles that have one or more clinical or historical signs of melanoma. Nevisense is intended for use when your doctor wants more information before deciding whether to remove a mole (or part of a mole) for biopsy, so that a pathologist, who is a doctor trained to examine tissue for signs of disease, can check whether the mole is melanoma. Nevisense should not be used when your doctor already feels sure that a mole is melanoma. Nevisense is one part of your doctor's evaluation, and does not replace your doctor's judgement.

What is melanoma, and how do dermatologists detect it?

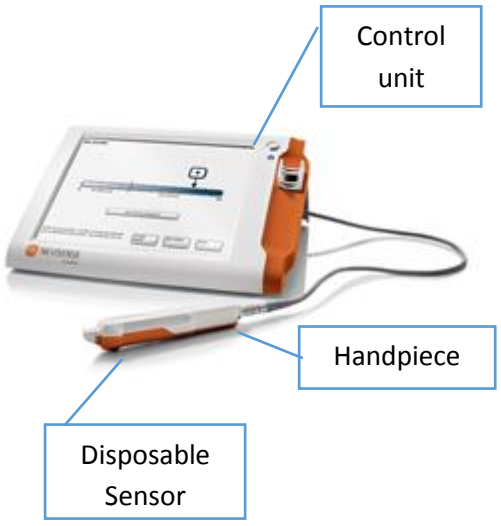
Melanoma is a type of skin cancer in which the color-producing cells of the skin grow out of control. Melanoma is the most serious form of skin cancer. It can spread to other parts of the body and can be fatal. If found and treated early, by complete removal, melanoma of the skin is often curable.

When checking suspicious moles for melanoma, doctors look at the size, shape, color and texture of the moles. They may also consider a patient's medical history and risk factors such as family history of skin cancer or history of severe sunburns. Based on all of this information, the doctor decides whether to remove the mole (or part of the mole) for biopsy. A biopsy means that the skin sample is looked at under a microscope by a pathologist, meaning a medical doctor trained to examine tissue to check for disease. The biopsy is used to confirm if the mole is melanoma.

When doctors examine a mole, they can normally tell by looking at it whether there are signs of melanoma. In more difficult cases, when a mole looks unusual, Nevisense provides additional information, to be used with the patient history and doctor's visual examination, to help the doctor decide whether to remove the mole for biopsy.

Nevisense Description

Nevisense measures how skin resists electrical signals, also called skin's electrical impedance. This reflects properties of the skin that cannot be seen, such as cell structure, shape, and size. These properties can differ in normal skin versus abnormal skin. Nevisense compares a measurement taken on your normal skin to measurements taken on your mole, and displays an electrical impedance spectroscopy (EIS) score. The EIS score gives your doctor additional information when deciding how likely it is that your mole is or is not melanoma.



Nevisense consists of a control unit, and a handpiece with a disposable sensor on the end. To take a measurement, your doctor presses the sensor against your skin.

Risks

Incorrect results

Possible risks of any skin check or test for melanoma include incorrect (false) results.

- A false negative means a mole is melanoma but the test wrongly says it is not, or says it has a low risk of being melanoma. A false negative may delay treatment of melanoma. This can lead to increased illness or death.
- A false positive is when a mole is not melanoma but the test wrongly says it is, or says it has a high risk of being melanoma. A false positive may result in removing a mole that is not melanoma.

The Nevisense device was tested in a pivotal clinical study on 1951 moles (including 267 melanomas) from 1915 patients. (See "Clinical Studies" section.) The moles were tested with Nevisense, and then removed and sent for biopsy to see if they were melanoma. Study doctors removed all moles without knowing the Nevisense results. In the study, Nevisense missed some melanomas (see false negatives below), and said some moles were melanomas that were not (see false positives below).

Results in the pivotal clinical study	
Incorrect Result Type	**Number of Study Moles**
False negatives	11 of 267 melanoma moles (4%)
False positives	1157 of 1684 non-melanoma moles (69%)

Adverse events

Out of 1915 patients, 12 patients (0.6%) had 14 adverse events that were related to Nevisense use. These events are described in the table below, in order of how often they occurred. No event was severe or serious.

Adverse Events in the pivotal clinical study that doctors thought were possibly, probably, or definitely related to Nevisense		
Event	**Patients Affected**	**Harm Description**
Bleeding	6 of 1915	Six patients had moles that bled during Nevisense use.
Pain	2 of 1915	Two patients had slight pain from the Nevisense handpiece, which stopped after the handpiece was removed.
Headache	2 of 1915	Two patients had a headache after Nevisense use and mole removal.
Tingling	2 of 1915	Two patients felt slight tingling (or pin-prick sensation) at the measurement site during the procedure.
Bruising	1 of 1915	One patient had very minimal bruising after four attempts to do the Nevisense measurement.
Itchiness	1 of 1915	One patient had an itch at the measurement site the next day.
The information in this table is based on use of the device at 22 clinics, on 1915 patients, over 18 months in this study. It is unknown whether other risks may occur, or how often the adverse events above may happen with more widespread device use.		

Other possible risks

If Nevisense fails to measure both the normal skin and the mole, then it will not provide an EIS result. In 100 of 1915 study patients, the Nevisense device was unable to measure the patient's normal skin and/or mole, and did not provide an EIS result.

If the Nevisense operator does not take enough measurements to cover the entire mole, the EIS result may be inaccurate, because it may not reflect the properties of the entire mole. In 57 of 1915 study patients, the operators did not take enough measurements to cover the mole.

If Nevisense measurements are done incorrectly, such as by measuring healthy skin instead of the mole, or not preparing the skin according to directions, the Nevisense result may be inaccurate. In 17 of 1915 patients, the Nevisense measurements were done incorrectly.

A negative Nevisense result (EIS score 0-3) does not eliminate the possibility that a mole is or may develop into melanoma.

The safety and effectiveness of Nevisense have not been established for:

- Patients with skin that rarely burns and tans profusely, or with skin that never burns and is deeply pigmented.
- Patients 30 years of age and under.

There may be other risks of device use or misuse that did not occur in the study and that are unknown at this time.

Benefits

When doctors examine a mole, they look at it with the naked eye and sometimes also with the aid of a dermatoscope (a special magnifying lens and light) to investigate whether there are signs of melanoma and whether a mole should be removed for biopsy. For more difficult cases, when a mole looks unusual, but not obvious or highly suspicious of melanoma, doctors may use Nevisense to obtain additional information to help determine whether a biopsy is needed.

The results of the clinical studies (see "Clinical Studies" section) suggest that Nevisense can aid dermatologists in detecting melanoma. It is unknown whether use of Nevisense by your doctor will directly benefit you.

What to expect from the Nevisense Procedure

First, your doctor will look closely at your mole. If your doctor believes the mole looks like melanoma, he or she may recommend it be removed for biopsy to confirm if it is melanoma. If your mole is difficult to evaluate based on visual methods alone, your doctor may recommend checking your mole with Nevisense. Nevisense provides additional information to help your doctor decide if a mole should be removed for biopsy.

The Nevisense procedure is simple and is typically painless. In the pivotal clinical study, 3 out of 1,915 patients reported slight pain or a mild tingling or pin-prick sensation during measurement.

Nevisense measurements are taken by pressing the sensor against your skin. Before each measurement the skin is cleaned and then moistened with saline solution to ensure good contact between the sensor and the skin.

The operator will perform one measurement on normal healthy skin close to the mole, and then one or more measurements on the mole itself. The operator must take enough measurements to cover the entire mole, so larger moles will require more measurements. The time required for the procedure depends on mole size and the number of moles to be measured. The procedure can be performed during a normal doctor visit.

After the measurements have been performed, the Nevisense results are displayed for your doctor. The result is presented as positive or negative, with a score between 0-10. Your doctor may use the result together with other clinical assessments and your medical history to decide whether or not the mole should be removed for biopsy.

If the score from your mole is positive (score 4-10), it does not necessarily mean that the mole is melanoma. A positive score means a greater risk that the mole may be melanoma, and the risk that the mole is melanoma increases with a higher score.

If the score from your mole is negative (score 0 – 3), this does not eliminate the risk that the mole is or may develop into melanoma. In the pivotal clinical study, when the result was negative (score 0 – 3), the chance that the mole was not melanoma was 98%.

Clinical Studies

The safety and effectiveness of Nevisense was tested in a pivotal clinical study of 1951 moles from 1915 patients. The study was conducted at 22 locations in the US and Europe.

All study doctors were dermatologists, meaning doctors specially trained to recognize and treat skin diseases. They and their clinical staff were trained by SciBase in the use of the device. Study patients were recruited from the study doctors' practices. Study patients were men and women of any ethnic group, aged 18 years or older, who had moles that their doctors chose to remove.

All study moles were selected for removal based on normal visual methods alone, and study doctors were not given any Nevisense information. Study moles were tested with Nevisense, and then removed and evaluated by an expert panel of pathologists (meaning doctors trained to examine tissue for signs of disease) who decided if the moles were melanoma.

The safety of Nevisense was evaluated by reviewing all adverse events that happened to study patients. Twelve of 1915 patients reported 14 adverse events that study doctors thought were possibly, probably, or definitely related to Nevisense. Please see the table describing these events in the Risks section. No adverse events were severe or serious.

The ability of Nevisense to tell melanoma from non-melanoma moles was evaluated by comparing the Nevisense results to the expert panel decisions. Nevisense correctly identified 256 of the 267 melanomas (96%). By comparison, a separate group of trained dermatologists who reviewed images of the study moles (for moles with sufficient image quality), correctly identified 181 of 254 melanomas (71.3%). And the local pathologists (meaning each clinic's pathologists, who were different from the expert panel) correctly identified 226 of 267 melanomas (84.6%). Nevisense also correctly identified 527 of the 1684 non-melanomas (31%).

A second "reader" study was conducted to see if having Nevisense information when deciding whether to remove moles would help doctors detect more melanomas. In the

reader study, forty-one doctors, who were all dermatologists, reviewed patient health and history information and photos of 141 moles, including 60 melanomas, from the pivotal clinical study. First, each doctor decided, based on the photos and patient information only (without Nevisense scores), if they thought each mole was melanoma and if they thought each mole should be removed for biopsy. Then each doctor decided again – but this time with the photos, patient information, and the additional Nevisense scores – if they thought each mole was melanoma and if they thought each mole should be removed for biopsy. Providing the Nevisense scores led to 158 more melanoma decisions and 121 more biopsy decisions for actual melanomas. Nevisense helped some doctors more than others, but no doctor in the study found fewer melanomas with Nevisense.

These study results suggest that Nevisense, when used with the visual examination, can help doctors when deciding whether to remove a mole for biopsy.

Your doctor makes the decision

Your doctor will use her/his clinical experience and judgment on when to use Nevisense and how to use the outcome of the measurement.

For Further Information

Visit www.scibase.com for more information

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