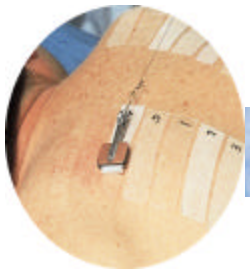

3M ä Medical Specialties

Frequently Asked Questions

February 2004

CLINICAL DATA SUMMARY – What do they mean?

Described below are general descriptions of some common biocompatibility studies used to test 3M Medical Specialties products. All tests are not necessarily conducted on every product and test methods may vary. The test results are typically based on limited exposure of test product to intact skin.

The tests are in accordance with the ISO 10993 Part 1 "Biological Evaluation of Medical Devices".

Cytotoxicity (Agar Overlay - generally considered a screening test)

Agar is poured over a continuous layer of mouse fibroblast cells growing in a culture plate. The test sample is placed over the agar. Soluble components (moieties) from the test sample diffuse through the agar and interact with the cells. If the moieties are toxic, the cells die. Adding a stain to the agar helps detect the cell death (lysis) and the lysis zone around the test sample. Cytotoxicity is reported as "response index", which is a ratio of the zone index to the lysis index.

Cytotoxicity Rating	Descriptive Rating
0.0	Not cytotoxic
0.1-0.9	minimal
1.0-1.8	mild
1.9-2.8	moderate
2.9-4.0	severe
>4.0	extreme

Irritation Testing

These tests estimate the potential of a material to cause damage to tissue, i.e. irritation. Animal and/or human subjects may be used during testing.

Primary Skin Irritation

The test sample is applied to intact or abraded albino rabbit skin and over wrapped with gauze to hold it in place. Depending on the protocol, observations may be made at 4, 24, 48, and/or 72 hours. Scoring for dermal irritation is in accordance with the Draize procedure.

Tests are scored using a rating scale of 0-8 for both erythema (redness) and edema (swelling). Zero indicates no irritation. The results are reported as an irritation score ratio, e.g., 1.0/8.0. In this example the numerator, 1.0, is the average of the total erythema and edema observed for all animals

in the test. The denominator, 8.0, is the highest irritation score possible. The ratio is classified according to the following scale:

Mean PI Score	Descriptive Rating
0	Non- irritating
0.1 - 0.5	Minimally Irritating
0.6 -1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 -5.0	Moderately Irritating
5.1 -6.5	Severely Irritating
6.6 -8.0	Extremely irritating

Human Cumulative Irritation Patch Test (HCIPT) –This is a 21-day test that is conducted on approximately 20 humans to predict the potential for a material to cause skin irritation with chronic use. The test material is reapplied daily to the same site and worn for 23 hours each day. Skin condition is evaluated one-hour post removal.

Sensitization Testing

Sensitization tests estimate the potential of a material to cause contact sensitization. The testing may be done using animals and/or human subjects.

Guinea-Pig Sensitization or Buehler Test

The repeated-patch, or Buehler test consists of an induction phase and a challenge phase. The induction phase involves exposing the shaved backs of guinea pigs to the test sample, covered by an occlusive dressing, for a minimum of six hours. This procedure is repeated up to three times a week for three weeks. Following a two-week rest or recovery period to allow for the development of a delayed response, the animals are challenged using a final exposure to a patch of the test material. The skin conditions are scored after a pre-selected time interval.

Human Repeat Insult Patch Test (HRIPT) – This test is conducted on a large number (typically 100 – 200) of human subjects to determine the sensitization potential of a material.

The test consists of an induction phase and a challenge phase. The induction phase typically lasts for three weeks during which test articles are applied to the backs of subjects every second day. Skin conditions are scored at 24 and 48 hours, although other time intervals may be chosen.

The challenge phase is conducted two weeks after the conclusion of the induction phase. A sample of the test material is applied to the skin at a new (not previously exposed to the test sample) site for twenty-four hours. Skin condition is evaluated 48 and 96 hours after removal of the sample.

CLINICAL DATA SUMMARY – What do they mean?

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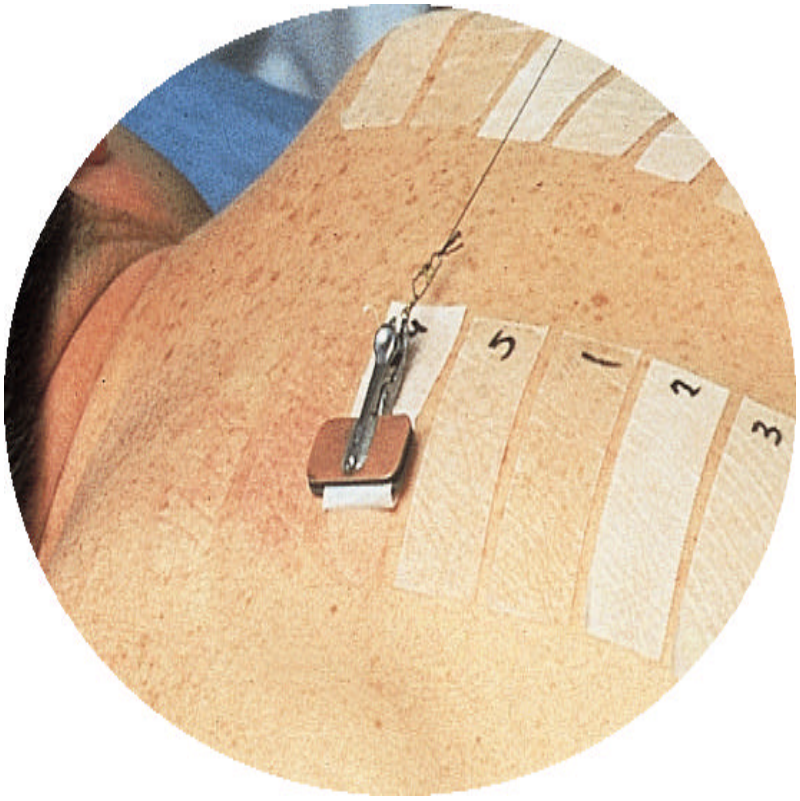
Skin Adhesion Testing by In House Panel (IHP) – This test measures adhesion to human skin using a small number of subjects (typically 6-12). The test tapes are usually applied to the back and adhesion levels are measured at various times after application; typically immediately after application (T=0), after 4 hours (T=4) and again after 24 hours (T=24). The results of this test provide a skin adhesion profile over time.

Skin adhesion results between tapes should not be directly compared unless the tapes were tested side-by-side in the same study. It is important to note that Skin Adhesion values are for reference purposes only and should not be considered a specification. Skin adhesion levels vary with individuals. Even on the same individual, skin adhesion values can change with the season, activity level, general health condition etc.



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To have a sales representative contact you, to request samples or clinical and safety summaries, please contact us at 3M HELPLINE 800-228-3957 (U.S.) or 651-604-5599 (International).

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