



HAZARD AND SAFETY INFORMATION

Indicator® Markers

IZI Medical Products, LLC is pleased to provide the following information regarding Hazard and Safety Information for the Indicator Marker products. While the US Food and Drug Administration (FDA) does not require medical device manufacturers to maintain MSDS for finished medical devices IZI maintains a MSDS for raw materials that are used to manufacture finished products. Materials used to fabricate components, and eventually devices that come in contact with humans are tested for biocompatibility at independent laboratories. As always, the results of these tests are included in our Device Master Records as required by FDA Regulations.

It is the policy of IZI Medical Products, LLC to comply with Federal Regulations, International Regulations, and Industry Standards for Medical Device manufacturing.

All sterility processes used to manufacture IZI products were developed to comply with applicable governmental regulations, standards, and American Association of Medical Instrumentation (AAMI) guidelines.

HEALTH HAZARD DATA

Exposure Route	Finding	Basis
Eye Contact	Not an irritant	Markers are not intended for use on or directly proximal to the eyes. Ink is non-toxic in the event of casual contact.
Skin Contact	Not an irritant	Medical Grade adhesive material has been tested and found not to be significantly irritating or a sensitizer to animals or humans
Skin Absorption	Not Expected to be Toxic	Ink is cured to stability during production and is not expected to be absorbable into the skin. Does not contain latex.
Inhalation	Not Expected to be Toxic	Not a possible route of exposure.
Ingestion	Not Expected to be Toxic	Materials are not intended to be ingested, however all materials are non-toxic and not expected to cause adverse effects.

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