

Labeling for Keystone Industries' products may contain internationally recognized symbols. Below is an explanatory glossary of symbols used on product labeling.

Ref: Current International Standards- ISO 15223			
Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied			
Symbol	Symbol Ref. No.	Symbol Title	Additional Information
	5.1.1	Manufacturer	Symbol is accompanied by the name and address of the legal manufacturer.
	5.1.2	Authorized representative in the European Community	Symbol is accompanied by the name and address of the authorized representative.
	5.1.3	Date of manufacture	This symbol is shown with an adjacent date to indicate the date of manufacture shown as YYYYMMDD.
	5.1.4	Use-by date	Synonym for "use-by date" is "use by." Will precede the identified use by/expiration date of the device
	5.1.5	Batch code	Synonyms for "batch code" are "lot number" and "batch number."
	5.1.6	Catalogue number	Synonyms for "catalogue number" are "reference number" and "reorder number."
	5.1.8	Importer	To indicate the entity importing the medical device into the locale. The symbol is accompanied by the name and address of the importing entity located adjacent to the symbol.
	5.1.9	Distributor	To indicate the entity distributing the medical device into the locale. The symbol is accompanied by the name and address of the distributor entity located adjacent to the symbol.
	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process. *this symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
	5.2.8	Do not use if package is damaged and consult instructions for use	This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised." For products that do not have instructions for use, the recommendation to consult them does not apply.
	5.3.1	Fragile, handle with care	

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Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied

Symbol	Symbol Ref. No.	Symbol Title	Additional Information
	5.3.2	Keep Away From Sunlight	Medical device that needs protection from light sources and/or heat
	5.3.4	Keep dry	Device needs protection from moisture
	5.3.7	Temperature limit	 <p>In the example shown, the lowest temperature for product storage is 32°F/0°C and the highest 86°F/30°C</p>
	5.4.2	Do not re-use	Do not reuse the device/Single Use only
	5.4.3	Consult instructions for use or Consult electronic instructions for use	<p>“Consult instructions for use” or “Consult operating instructions.”</p> <p>When used to indicate an electronic instruction for use (eIFU) this symbol is accompanied by an eIFU indicator which may represent the manufacturer’s website or any other appropriate indication on the use of the eIFU the indicator may be placed next to, above or beneath the symbol</p>
Sample per A.16 of symbol 5.4.3		The eIFU indicator may be a manufacturer’s website URL or some other appropriate indication that the IFU is available in electronic format	
	5.4.4	Caution	User should consult the instructions for use for important cautionary information such as warnings and precautions which are not present on the product label.
	5.7.7	Medical Device	Indicates the item is a medical device according to the EU Regulation 2017/745.
	5.7.10	Unique device identifier	This symbol may be used when multiple data carriers are present on the label. Keystone’s format is the HIBBC defined layout

Other Marks and Symbols

Symbol	Symbol Description	Additional Information
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician, dentist or health care professional.	USA Code of Federal Regulations 21 CFR Part 801 § 801.109(b)(1)
	European Conformity mark	The product conforms to European Medical Directive 93/42/EEC/ or Medical Device Regulation 2017/745 as applicable and meets applicable health, safety and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	Product does Not contain Latex	
 Warning:	State of California Prop 65 warning	