

# Non-Sterile, Single Use, Bulk Hypodermic Needles

## INSTRUCTION FOR USE (IFU)

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BS EN ISO 7864:2016 Compliant

JMI HOSPITAL REQUISITE MFG. LTD. is the leading manufacturer of Bulk Hypodermic Needles and medical devices at Bangladesh serving the health care community both here and across our borders. JMI is a joint venture enterprise with Republic of Korea. With the technical collaboration of Star Syringe Ltd.

### DESCRIPTION:

Hypodermic Needles is designed to aspire / inject fluid under the skin (hypodermic) and/or other soft tissues. These needles consist of hollow, sharply pointed, stainless steel cannula with the distal end finished in a connector (female Luer slip) that can be easily attached to a syringe or tube or catheter. Hypodermic needles have a small diameter (18 to 27 gauge) and length (14 to 38 mm [0.5 to 1 inch]) (UMDNS 12745). This is a single-use device. This is a single-use device. Syringe is primarily for use in humans.

**INDICATIONS:** Hypodermic Needle is designed to aspire / inject fluid under the skin (hypodermic) and/or other soft tissues. These needles consist of hollow, sharply pointed, stainless steel cannula with the distal end finished in a connector (Female Luer slip) that can be easily attached to a syringe or tube or catheter. This is a single-use device. Hypodermic needles have a small diameter (18 to 27 gauge) and length (13 to 25 mm [0.5 to 1 inch]) (UMDNS 12745 Needles, Injection, Hypodermic).

**USE WITH OTHER DEVICES:** Hypodermic Needle is used in combination with any Hypodermic Syringe or Catheter having male small bore luer slip connector (L1) with dimensions compliant with BS EN ISO 80369-7:2017; to perform its intended use of aspiration and/or injection of fluid under the skin. USP / EP compliant injectables are used with Hypodermic Needle.

**CAUTION: hypodermic needle are not intended for dental purposes.**

**Non-Sterile, Single Use, Bulk Hypodermic Needles are not intended for direct use on patient. Bulk hypodermic needle is supplied to manufacturers of syringe and/or IV cannula manufacturers for assembly & packaging on manual or automated machines and EO sterilization before placing on market.**

**APPLICATION:** Hypodermic Needle (hypodermic means 'beneath the skin') consist of a hollow needle attached to a syringe or cannula. Needle pierce the skin and aspirate or inject fluids / injectables beneath the skin.

**PATIENT GROUPS:** hypodermic needles can safely be safely used for patient groups of Adults (above 18 years), Children (between 1 year to 18 years), Infants (below 1 year), Pregnant & Lactating Women.

**ADVERSE REACTIONS:** No adverse reactions yet reports.

**STORAGE:** Recommended storage conditions: below 35°C, away from moisture and direct heat. Do not use after the expiry date.

**STERILITY (STERILIZATION):** auto-disable hypodermic syringes are supplied in Non-Sterile condition.
















**PRE-USE CHECKS:** Inspect the packaging & label very carefully for Lot, manufacturing & expiry dates. Do not touch: the shaft of the needle, the bevel of the needle, the adapter of the needle. Do not touch any part of the needle.

**HOW TO USE NON-STERILE, SINGLE USE, HYPODERMIC NEEDLE:** Bulk hypodermic needles are not intended for direct use on patient. Bulk hypodermic needle is supplied to manufacturers of syringe and/or IV cannula manufacturers for assembly on manual or automated machines and EO sterilization before placing on market. De-Dusting of shipper carton is recommended at the time of receiving bulk hypodermic needles. Remove shipper carton in un-controlled environment outside the clean room. Remove secondary polybag before transfer the bag in clean room. Discard packaging / packing material after use in environmentally friendly manner.

### WARNINGS / PRECAUTIONS / INTERACTIONS:

- ⚠ Ensure that the packaging is intact and no signs of damage. Inspect Label information prior to use.
- ⚠ Do not remove needle cap. If cap is missing discard the needle and don't
- ⚠ If needle is bent or damaged, no attempt should be made to straighten needle or use the product.
- ⚠ Do not store at extreme temperatures & humidity. Avoid direct Sunlight.
- ⚠ Do not use after expiry date.

### SYMBOLS USED ON LABELLING:

	Manufacturer
	Authorized representative in the European community
	Catalogue number
	Batch code
	Consult instruction for use
	Non-Sterile
	Do not reuse
	Latex Free or Not Made With Natural Rubber Latex
	Does not contain the phthalate plasticizers DEHP, DIBP, DBP, or BBP
	Non-Pyrogenic
	Store below 35°C
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Use by (month & year)



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