

EN

Disposable Hypodermic Needle

REF	Gauge	Length (in)	Hub Color
26400	27G	1/2"	Medium Grey
26401	26G	3/8"	Brown
26402	26G	1/2"	Brown
26403	25G	5/8"	Orange
26405	25G	1"	Orange
26406	25G	1"1/2	Orange
26407	23G	3/4"	Deep Blue
26408	23G	1"	Deep Blue
26409	23G	1½"	Deep Blue
26410	22G	3/4"	Black
26411	22G	1"	Black
26412	22G	1½"	Black
26413	22G	1-1/4"	Black
26414	21G	1"	Deep Green
26415	21G	1-1/4"	Deep Green
26416	21G	1½"	Deep Green
26417	20G	1"	Yellow
26418	20G	1-1/12"	Yellow
26419	18G	1"	Pink
26420	18G	1½"	Pink
26421	16G	1"	Purple
26423	16G	3/4"	Purple
26424	19G	1"	Cream
26425	25G	3/4"	Orange
26426	27G	1½"	Medium Grey
26427	27G	1¼"	Medium Grey
26430	20G	3/4"	Yellow
26431	20G	1/2"	Yellow
26436	22G	1/2"	Black
26437	30G	1/2"	Yellow
26438	19G	1½"	Cream
26439	30G	1"	Yellow
26448*	28G	3/4"	Blue-Green
26460	20G	2"	Yellow
Hard Pack Needles			
26391	31G	1/2"	White
26392	32G	1/2"	Deep-Green
26392S	32G	1/2"	Deep-Green
26393	33G	1/2"	Black

^{*27} Inner Diameter





Instructions For Use (IFU)

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1 <u>Device Description</u>

1.1 The hypodermic needle is a single-use, sharp bevel-edged, hollow tubular device intended to be inserted beneath the skin of a patient while connected to a non-invasive device to administer and/or withdraw (aspirate) fluids/drugs; it may also be used for fluid/drug preparation.

2 Intended Use

2.1 The hypodermic needle is used in conjunction with syringes, and infusion/transfusion sets to inject fluids into, or withdraw fluids from, the body.

3 Indications for Use/Target Users

- 3.1 Hypodermic needles are equipped with a male Luer/Luer lock connector that can be used in conjunction with syringes and infusion/transfusion sets.
- 3.2 The device is designed for use by a qualified physician or clinician.
- 3.3 Hypodermic needles are indicated for use with the general patient population.

4 Benefits of Use

- 4.1 Safe, easy to use.
- 4.2 Sharp, stainless-steel needle.
- 4.3 Rapid delivery of fluids.
- 4.4 Prevent cross-contamination between patients.
- 4.5 Each needle is individually packaged, sterilized, and ready for use.



5 Warnings/Precautions

- 5.1 Handle with care to avoid needle sticks.
- 5.2 Do not replace original needle cover after use.
- 5.3 Use once and discard immediately in accordance with local safety standards.
- 5.4 If needle is bent or damaged, no attempt should be made to straighten needle or use the product.
- 5.5 Do not bend or apply extra force on the needle tube as it may lead to needle tube breakage when the bending angle exceeds 25° for regular-walled needle tube and 20° for thin wall.
- 5.6 For single use only.
- 5.7 Do not reuse. Reuse of needle can result in contamination or transmit disease.
- 5.8 Do not reprocess.

6 Contraindications

6.1 There are no recognized contraindications for the use of hypodermic needles.

7 Sterility

- 7.1 Hypodermic Needles are sterilized by EO gas sterilization (indicated by STERILE[E0]) single use only.
- 7.2 Do not re-use 2
- 7.3 Do not re-sterilize.
- 7.4 Inspect each package prior to use.
- 7.5 Do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened the device must be used or discarded.

8 Operating Instructions

- 8.1 Separate at upper package edge and peel apart to point below the hub.
- 8.2 Affix and tighten the syringe or female luer to the needle using aseptic technique. Grip the base of the needle and turn the syringe or luer clockwise.
- 8.3 Fill the syringe with fluid according to established technique.
- 8.4 Remove the needle cap and perform the procedure according to established technique.
- 8.5 After the procedure, discard of the needle in a biohazard container according to local safety standards.

9 Storage

- 9.1 Store at room temperature 15°C-25°C.
- 9.2 Do not store in high temperatures and humidity.
- 9.3 Keep away from direct sunlight.
- 9.4 Store in a cool and dry place.

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Graphic Symbol Legend for Medical Device Labeling

MD	Medical Device	
REF	Catalog number	
Ronly	Federal law (USA) restricts this device to sale by or on the order of a physician.	
Ţ <u>i</u>	Consult instructions for use	
\triangle	Important Cautionary Information	
STERILEEO	Sterilized by Ethylene Oxide. Sterility guaranteed if package unopened and undamaged.	
LOT	Manufacturer's Lot Number	
UDI	Unique Device Identifier	
	Use by	
M	Date of Manufacture	
2	For single-patient-use only. Do not reuse.	
STERINGE	Do Not Re-Sterilize.	
	Do not use if package is damaged	
漆	Keep away from sunlight	
Ť	Keep Dry	
15C°- 15C°	Temperature Limit	
×	Non-Pyrogenic	
	Single Sterile Barrier System with Protective Packaging Inside	
×	This device is not manufactured with Natural Rubber Latex	
**	Manufacturer	
C€	Product marketed in European countries	
EC REP	European Representative	

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