

Instructions for Use - EXEL Hypodermic Needle



| REF | Model | Hub Color |
|--------|--------------|-------------|
| 26391S | 31G x 1/2" | White |
| 26392S | 32G x 1/2" | Deep-Green |
| 26393S | 33G x 1/2" | Black |
| 26400 | 27G x 1/2" | Medium Grey |
| 26401 | 26G x 3/8" | Brown |
| 26402 | 26G x 1/2" | Brown |
| 26403 | 25G x 5/8" | Orange |
| 26405 | 25G x 1" | Orange |
| 26406 | 25G x 1 1/2" | Orange |
| 26407 | 23G x 3/4" | Deep Blue |
| 26408 | 23G x 1" | Deep Blue |
| 26409 | 23G x 1 1/2" | Deep Blue |
| 26410 | 22G x 3/4" | Black |
| 26411 | 22G x 1" | Black |
| 26412 | 22G x 1 1/2" | Black |
| 26413 | 22G x 1-1/4" | Black |
| 26414 | 21G x 1" | Deep Green |
| 26415 | 21G x 1-1/4" | Deep Green |
| 26416 | 21G x 1 1/2" | Deep Green |
| 26417 | 20G x 1" | Yellow |
| 26418 | 20G x 1 1/2" | Yellow |
| 26419 | 18G x 1" | Pink |
| 26420 | 18G x 1 1/2" | Pink |
| 26424 | 19G x 1" | Cream |
| 26425 | 25G x 3/4" | Orange |
| 26426 | 27G x 1 1/2" | Medium Grey |
| 26427 | 27G x 1 1/4" | Medium Grey |
| 26430 | 20G x 3/4" | Yellow |
| 26431 | 20G x 1/2" | Yellow |
| 26436 | 22G x 1/2" | Black |
| 26437 | 30G x 1/2" | Yellow |
| 26438 | 19G x 1 1/2" | Cream |
| 26439 | 30G x 1" | Yellow |
| 26460 | 20G x 2" | Yellow |

Specialty Use

| | | |
|-------|-------------------|------------|
| 26448 | 28G x 3/4" T.W. * | Blue-Green |
|-------|-------------------|------------|

*THIN-WALL (T.W.) NEEDLE SPECIFICATION

26448 features a thin-wall design for delivery of more viscous fluids; The "T.W." (thin-wall) designation indicates that the needle tube wall thickness falls within the thin-wall subrange defined by ISO 9626:2016 for 28-gauge tubing.
 - Outer Diameter 0.349-0.370mm (28G per ISO 9626:2016)
 - Inner Diameter 0.190-0.221mm (Thin-Wall specification per ISO 9626:2016)

1 Device Description

- 1.1 EXEL Hypodermic Needles are single-lumen hypodermic needles which are sterile and intended for single use. They consist of a hollow, beveled metal tube (the cannula) that is sharpened at one end and at the other end joined to a female connector (the hub) designed for connection to other devices (e.g., piston syringes, etc.). They are used to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. A protective cap is included to prevent needlestick injuries during transport and handling.
- 1.2 Models are differentiated by the needle gauge (the diameter of the sharpened metal tube) and the needle length (the length of the sharpened metal tube). The hub is pigmented according to ISO 6009 color-coding to facilitate visible identification of the needle gauge.
- 1.3 Models denoted with a "T.W." in the model name are thin-wall variants. Thin-wall variants are identified as being particularly effective when delivering more viscous fluids. They are also safe and effective for use in standard clinical applications.
- 1.4 Materials:
 - 1.4.1 Cover/Cap: PP (Ethylene/Polypropylene Copolymer)
 - 1.4.2 Color Coded Hub: PP (Ethylene/Polypropylene Copolymer). Attached to needle with epoxy resin.
 - 1.4.3 Needle: Stainless Steel with a coating of silicone oil on the exterior of the needle as a lubricant.

2 Indications for Use

- 2.1 These devices are intended to be used:
 - 2.1.1 to inject fluids into, or withdraw fluids from, the body.
 - 2.1.2 to administer and/or withdraw (aspirate) fluids/drugs.

3 Intended Users/ Patient Population

- 3.1 These devices are intended for use by qualified healthcare professionals in a professional healthcare environment.
- 3.2 These devices are intended for use in the general population, including both adult and pediatric patients of all age groups, as determined appropriate by the qualified healthcare professional using the device.

4 Clinical Benefits

- 4.1 Safe, easy to use.
- 4.2 Rapid delivery of fluids.
- 4.3 Prevent cross-contamination between patients.
- 4.4 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 the 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 Avoid bending or applying excessive force on the needle tube. Excessive force may lead to needle tube breakage. Do not exceed a bending angle of 20°.
- 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.
- 5.9 Not for intraocular use.
- 5.10 U.S Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

6 Contraindications

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

7 Risks

- 7.1 Infection at puncture site or where injection was made
- 7.2 Needlestick injuries
- 7.3 Contamination and transmission of disease or bloodborne pathogens

8 Side Effects

- 8.1 Hypersensitivity
- 8.2 Discomfort
- 8.3 Bruising
- 8.4 Bleeding
- 8.5 Redness
- 8.6 Irritation

9 Sterility

- 9.1 Hypodermic Needles are sterilized by EO gas sterilization.
- 9.2 Single use only. Do not reuse.
- 9.3 Do not resterilize.
- 9.4 Inspect each package prior to use. Do not use the device 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.

10 Operating Instructions

- 10.1 Separate at upper package edge and peel apart to point below the hub.
- 10.2 Affix and tighten the needle to the syringe (or other device with luer connector) using aseptic technique.
 - 10.2.1 For connection to devices with a Luer Lock
Tip: Push the needle hub onto the tip and twist clockwise until it is fully seated and secure.
 - 10.2.2 For connection to devices with a Luer Slip
Tip: Push the needle hub straight onto the tip until it is securely in place.
- 10.3 Remove the needle cap and perform the procedure according to established technique.
- 10.4 After the procedure, discard the devices in a biohazard container according to local safety standards.

11 Storage

- 11.1 Keep away from direct sunlight.
- 11.2 Keep dry.

NOTICE

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Any serious incident that occurs must be reported to the manufacturer and competent authority according to local regulations. EXELINT International, Co. disclaims any responsibility for possible consequences resulting from reuse, resterilization or improper use.



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


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Graphic Symbol Legend for Medical Device Labeling

| | |
|---|---|
|  | Medical Device |
|  | Catalog number |
|  | Federal law (USA) restricts this device to sale by or on the order of a physician. |
|  | Consult instructions for use |
|  | Caution |
|  | Sterilized by Ethylene Oxide. Sterility guaranteed if package unopened and undamaged. |
|  | Manufacturer's Lot Number |
|  | Unique Device Identifier |
|  | Use by date |
|  | For single-patient-use only. Do not reuse. |
|  | Do not re-sterilize. |
|  | Do not use if package is damaged |
|  | Keep away from sunlight |
|  | Keep Dry |
|  | Non-Pyrogenic |
|  | Single Sterile Barrier |
|  | Protective Packaging Outside of Sterile Barrier System |
|  | This device is not manufactured with Natural Rubber Latex |
|  | Manufacturer |
|  | Country of Manufacture |
|  | Product marketed in European countries |
|  | European Representative |
|  | Australian Sponsor |