BARRIGEL® APPLICATOR NEEDLE
INSTRUCTIONS FOR USE

DESCRIPTION

The Barrigel Applicator Needle is designed for injection of Barrigel. The patient contacting portion of the needle is silicone coated, 304 stainless steel. Gamma irradiation is used to sterilize the needle.

The Barrigel Applicator Needle is provided in a pouch with two needles.

ELECTRONIC IFU

A copy of this Barrigel Applicator Needle Instructions for Use document in pdf format is available at www.barrigel.com.au

In addition, paper copies of the Barrigel Applicator Needle IFU may be requested by calling 1800 794 401. A paper copy will be provided to the requestor free of charge in a timely manner.

NEEDLE SPECIFICATIONS

Diameter: 18 G (1.2 mm)
Length: 20 cm
Silicone coated
Stylet is included

INDICATIONS

The Barrigel Applicator Needle is used to inject Barrigel.

CONTRAINDICATIONS

None

WARNINGS

- This product may only be used by a qualified, licensed healthcare professional.
- This product is intended for use only with the Barrigel syringe. Refer to the Barrigel Instructions for Use before using the Barrigel Applicator Needle.
- DO NOT inject intravascularly. As with other injectable medical devices, inadvertent injection into blood vessels could potentially lead to vascular occlusion, distal embolization, ischemia, and necrosis.
- SINGLE USE ONLY – DO NOT REUSE. Reuse may result in needle fatigue or failure, or transfer of blood or tissue.
- DO NOT resterilize.
- DO NOT USE if the sterile package is damaged.
- DO NOT USE damaged product.
- DO NOT inject if the patient is known to be allergic to silicone.
- The Barrigel Applicator Needle has not been evaluated for MRI-related heating or migration. Use of this device in an MRI environment may cause device migration, MRI-related heating, and the MRI image may be compromised close to the position of the device.
- Once the needle pouch is opened, needles must be either used or discarded.
- DO NOT save or store unused needles from opened needle pouches.

PRECAUTIONS

- Before use, inspect for package integrity and for any damage that may affect sterility.
- Do not use product if the expiration date or lot number is missing or illegible on the packaging.
- Use aseptic techniques to remove the Barrigel Applicator Needle from the package.
- Injection procedures are associated with risk of infection. Aseptic techniques and standard practice to prevent preoperative infections must be observed.
- When positioning and orienting the location of the needle tip with ultrasound, the position of the needle bevel should be noted using the indicator on the needle hub.
- Positioning may be more difficult when changing syringes.
- Knowledge of the anatomy of the treatment site and special caution are required to avoid perforation of vessels, vulnerable organs, and rectal tissue.
- If the product is damaged or package integrity has been compromised, please contact the Palette Life Sciences Medical Information Department (contact information below).
- Care should be taken with the amount of force applied when handling the glass syringe and needle and with removal of the protective sheath to avoid laceration or other injury. The needle is lubricated, which decreases the amount of force needed to insert the needle.

POSSIBLE ADVERSE EVENTS

Anticipated procedure-related side effects are pain at the injection site and short-term transient injection site bleeding from the needle stick.

Other adverse events that may occur after the injection of Barrigel include injection site discomfort, injection site irritation, injection site bleeding, or hematoma and injection site inflammation.

Care should be taken when handling the glass syringe and needle to avoid laceration or other injury.

INSTRUCTIONS FOR USE

1. Verify labeling to ensure understanding and confirm product is within its expiration date before use. Inspect package carton and product pouch to ensure they are not damaged.
2. Product is provided with a protective sheath covering the sharp needle tip. Carefully remove needle(s) from the packaging to avoid mishandling the needle(s), which could lead to laceration from the sharp tip and/or contamination of the needle(s).
3. Strict aseptic technique must be followed. Improper assembly may result in separation of the needle and syringe during injection. To avoid any interruption in patient treatment, it is recommended that extra syringes and needles be kept in inventory.

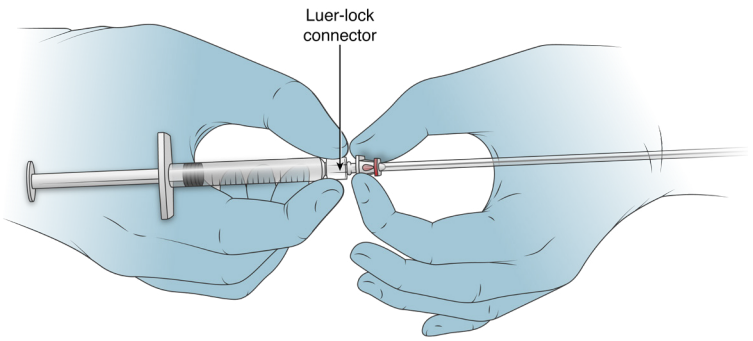
4. Needle preparation and insertion:

   a. If stylet is not used during needle insertion:
   - i. Remove stylet from the needle.
   - ii. Assemble the needle to the Barrigel syringe[1] and remove the protective sheath from the needle.
   - iii. Prime the needle by extruding a small amount of Barrigel from the tip of the needle.
   - iv. Insert the needle using the appropriate imaging guidance.

   b. If stylet is used during needle insertion:

   Please note: If using a stylet, insert needle past the desired injection area. Expel the air into an area where its presence will not affect visualization. Once all air is expelled, move the needle into the injection area and follow the treatment protocol detailed below.

   - i. Remove protective sheath from the needle.
   - ii. Insert the needle using the appropriate imaging guidance.
   - iii. Remove stylet from the needle.
   - iv. Assemble needle to Barrigel syringe[1].



[1]Use the thumb and forefinger to grasp the needle by the hub. With the other hand, hold the syringe by the luer-lock connector. Important: DO NOT hold the glass syringe body. Connect and twist while holding the luer lock and hub. Create a firm connection (DO NOT overtighten).

5. Verify needle tip location before injecting Barrigel.
6. Inject Barrigel.
7. When replacing an empty syringe, hold the needle in place, carefully remove the empty syringe, and attached a new syringe.[1]
8. If more than one needle is used for the procedure, repeat steps 1-7.
9. Withdraw needle and syringe assembly from the patient.

DISPOSAL

DO NOT RE-SHIELD USED NEEDLES. The syringe, disposable needles, and any unused material must be discarded immediately after treatment. Do not reuse due to risk of contamination of the unused Barrigel material, as well as associated risks including infection. Disposal must be in accordance with accepted medical practice and applicable national, local, and institutional guidelines. Discard the used needles and syringes in a sharps disposal container or using standard hospital sharps disposal procedures.

MANUFACTURER

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SYMBOLS

	Manufacturer		Sterilized Using Irradiation
	Caution		Do Not Use if Package is Damaged and Consult Instructions for Use
	Consult Instructions for Use barrigel.com.au		Do Not Resterilize
	Batch Code		Use-by Date
	Catalogue Number		Prescription Only - Device Restricted To Use By or on the Order of a Physician
	Do Not Re-use		

For product information, adverse event reporting, and product complaint reporting, please contact:

Palette Life Sciences Medical Information Department - AU

PHONE: 1800 794 401
EMAIL: palettemc@eversana.com