



FDA-Compliant Avastin® Repackaging Service

Leiters Health was the first 503B outsourcer to introduce and provide Avastin (bevacizumab) repackaging services in accordance with the FDA's 2018 Final Guidance for the Repackaging of Biologics. In order to comply with the FDA Guidance for Biologics Repackaging, we utilize an optimized aseptic process that includes advanced filtration to meet the USP <789> reduced particulates standard for ophthalmic solutions.

As part of our ongoing commitment to quality we are pleased to announce the addition of the StaClear syringe to our Avastin repackaging service. StaClear is the first syringe to meet the FDA's stringent requirements for an intravitreal indication for use (510(k) Number K200242).

StaClear luer slip syringes are available for the following product:

Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F1056	71449-091-99	Bevacizumab 2.25 mg/0.09 mL (repackaged), StaClear® syringe	0.09 mL	0.25 mL syringe	150	10

THE LEITERS HEALTH CONVENIENCE FILL PROVIDES PHYSICIANS WITH AN EDUCATED NEEDLE CHOICE

Leiters Health recognizes that a physician's choice of syringe and injection needles has an impact on dosing accuracy due to the retained fluid in the needle/syringe combination. Due to variable fluid retention (i.e. dead space), the volume of Avastin that is delivered to the patient depends on the combination of syringe, fill volume, and needle selection.

To better inform our customers, Leiters Health polled retina customers to determine the most used needles for intravitreal injections and conducted extensive internal testing of these needles with Leiters Health's repackaged Avastin and the StaClear syringe. **Please contact your Leiters Health representative for a copy of the needle data test results.**

STACLEAR SYRINGE FEATURES AND BENEFITS²:

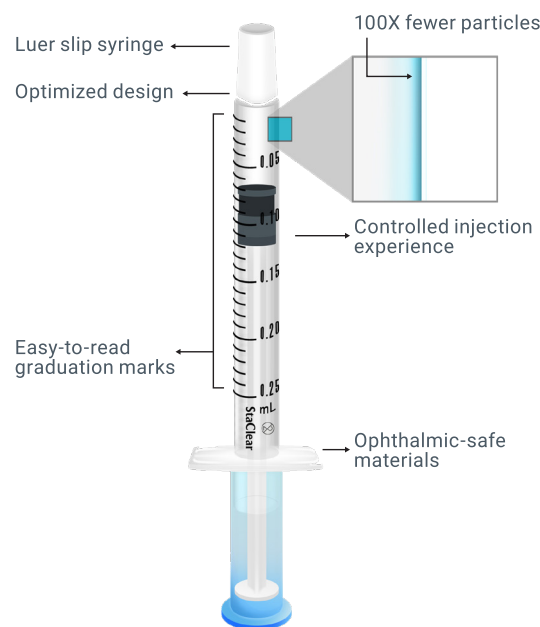
- Cleared by FDA for intravitreal injections (510K 200242).
- Meets the FDA's chemical and biocompatibility standards for ophthalmic use.
- Polydimethylsiloxane slip agent is crosslinked and fixed onto the syringe barrel surface, creating an ultra-low particulate.
- Easy-to-read graduation marks.

THE LEITERS HEALTH DIFFERENCE MAKES A DIFFERENCE FOR YOUR PATIENTS:

- In order to comply with the FDA Guidance for Biologics Repackaging, we utilize an optimized aseptic process that includes advanced filtration to meet the USP <789> reduced particulates standard for ophthalmic solutions.
- A Certificate of Analysis (CoA) detailing the testing is provided with every shipment.
- USP <789> compliant for visible and subvisible particulates.
- 150-day beyond use date (BUD)³.
- Compact space-saving tray to maximize refrigeration space at your facility.

BENEFITS OF ORDERING FROM LEITERS HEALTH:

- We source Avastin, so you don't have to.
- Inventory on hand to fill your order today.
- Same-day shipping for all orders⁴.



Orders & Inquiries

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