



StaClear® syringes now available for the Leiters Health FDA-Compliant Avastin® Repackaging Service

Leiters Health was the first 503B outsourcer to introduce and provide repackaged Avastin (bevacizumab) in accordance with the FDA's 2018 Final Guidance for the Repackaging of Biologics¹. In addition to meeting the FDA Guidance we also utilize an **advanced filtration process** which results in **reduced particulates**.

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 now available for the following products:

- F1042, "Econo-Fill" (0.08 mL fill) - provided with a TSK 30G x ½ inch low dead space needle (unattached).
- F1045, "Convenience-Fill" (0.11 mL fill) provides for physician needle choice.

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. **Leiters Health's internal test results are presented in the Needle Data Table below and the Needle Data Chart on the next page.**

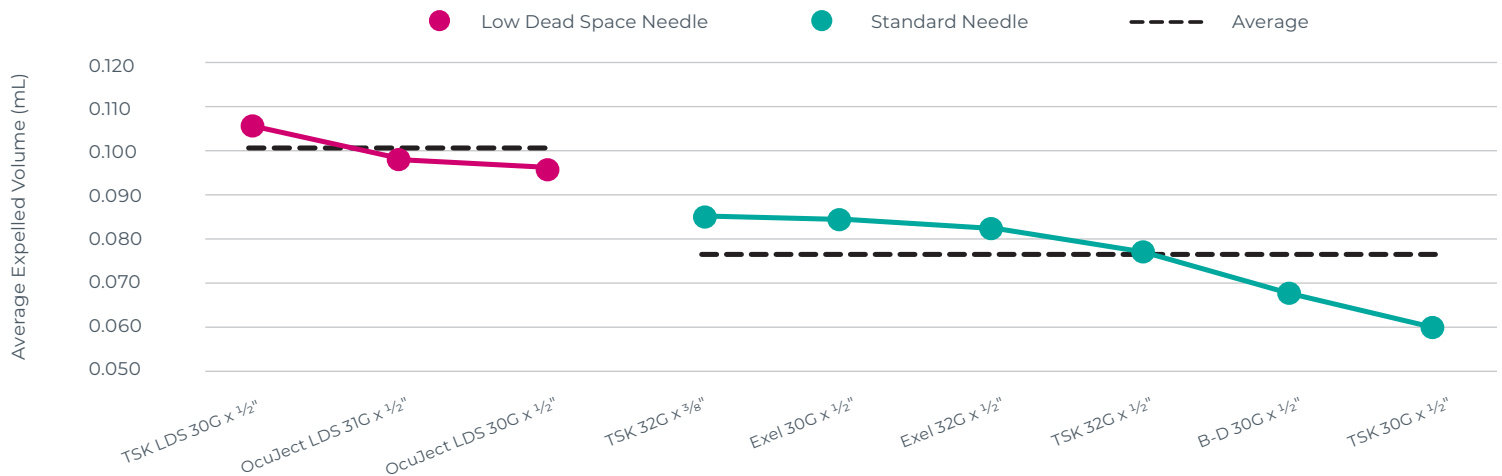
Item Number	NDC	Item Description	Fill	Container	BUD (days) ¹	Pack size
F1042	71449-091-22	Bevacizumab 2 mg/0.08 mL (repackaged), StaClear® syringe	0.08 mL	0.25 mL syringe	150	10
F1045	71449-091-90	Bevacizumab 2.75 mg/0.11 mL (repackaged), StaClear® syringe	0.11 mL	0.25 mL syringe	150	10

NEEDLE DATA TABLE

FILL QUANTITY = 0.11 mL			EXPRESSED NEEDLE VOLUME OF AVASTIN (mL)		
NEEDLE NAME/MANUFACTURER	NEEDLE SIZE	NEEDLE TYPE	MINIMUM	MAXIMUM	MEAN
B-D PrecisionGlide™	30G x ½"	Standard	0.059	0.078	0.069
Exelint International Exel®	30G x ½"	Standard	0.071	0.092	0.086
Exelint International Exel®	32G x ½"	Standard	0.077	0.102	0.082
TSK STERiJECT	30G x ½"	Standard	0.058	0.070	0.062
TSK STERiJECT	32G x ½"	Standard	0.059	0.089	0.078
TSK STERiJECT	32G x ⅜"	Standard	0.072	0.094	0.086
OcuJect OCUSAFE®	30G x ½"	Low dead space	0.091	0.104	0.098
OcuJect OCUSAFE®	31G x ½"	Low dead space	0.074	0.106	0.100
TSK LOW DEAD SPACE	30G x ½"	Low dead space	0.086	0.112	0.105



NEEDLE DATA CHART



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:

- We utilize an advanced filtration process prior to repackaging the Avastin per FDA Guidelines which results in reduced particulates.
- 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.

