FACT SHEET FOR HEALTHCARE PROVIDERS

MediBeacon®
Transdermal GFR System

June 9, 2026

Point of Care GFR Assessment

This Fact Sheet informs you of the probable risks and benefits of the use of the MediBeacon® Transdermal GFR System (TGFR).

Indications for Use

The MediBeacon® Transdermal GFR System (TGFR) is intended to assess the Glomerular Filtration Rate (GFR) in adult patients with impaired or normal renal function by noninvasively monitoring fluorescent light emission from an exogenous tracer agent over time. This device has been validated in patients with stable renal function.

The MediBeacon® TGFR is not approved for use in patients with GFR <15 ml/min/1.73m^2, GFR >120 ml/min/1.73m^2, patients on dialysis, or anuric patients. The use of this device in patients with dynamic and rapidly changing renal function has not been validated. This device is not intended to diagnose acute kidney injury (AKI).

The MediBeacon® TGFR Disposable Ring and the exogenous tracer agent, Lumitrace® injection, are single use and are only used with the MediBeacon® TGFR.

The MediBeacon® TGFR Disposable Ring is intended to be assembled with the MediBeacon® TGFR Reusable Sensor and attaches to the patient's skin during a TGFR session.

The MediBeacon® TGFR Reusable Sensor is intended to excite fluorescence in Lumitrace® injection, the tracer agent, and measure the returning light intensity. The data is sent to the MediBeacon® TGFR Monitor.

Lumitrace® is an injectable exogenous fluorescent tracer indicated for use with the MediBeacon® Transdermal GFR System (TGFR) for Glomerular Filtration Rate assessment.

Contraindications: There are no known contraindications.

All patients will receive the Fact Sheet for Patients: MediBeacon® Transdermal GFR System.

What is the MediBeacon® Transdermal GFR System (TGFR)?

The MediBeacon® Transdermal GFR System (TGFR) provides an assessment of glomerular filtration rate (GFR) at the point of care. This system employs an intravenously administered fluorescent tracer agent which has been engineered to be excreted exclusively by the kidneys. Noninvasive transdermal fluorescence detection of the excretion rate of the agent is converted into a GFR reading by this system.

The Instructions for Use can be found at IFU.MediBeacon.com.

What fluorescent tracer agent is used as part of the TGFR?

The MediBeacon TGFR includes Lumitrace (relmapirazin), an exogenous GFR tracer agent administered as an IV bolus injection.

Full prescribing information can be found at IFU.MediBeacon.com.

℞ only

- **Not for use in patients with dynamic or rapidly changing kidney function.**
- **Lumitrace® injection has light absorbance at 266 nm and 435 nm, and broad fluorescent emission at ~560 nm when excited at ~440 nm. Any drug activated at these wavelengths should not be used in conjunction with Lumitrace.**
- **Lumitrace® injection may interfere with clinical laboratory tests. DO NOT ADMINISTER if the patient is expected to need clinical laboratory testing while Lumitrace is present in their system, which may be for up to 72 hours.**

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

TGFR Key Components:

- Lumitrace® (relmapirazin) injection is the novel and proprietary fluorescent tracer agent, intravenously administered to a patient and then subsequently excreted from the body by the kidneys.
- MediBeacon® TGFR™ Reusable Sensor is a multiuse sensor containing the light source and photo detector for the noninvasive detection of the transdermal fluorescence from Lumitrace injection and is attached to one of several positions on the body using a biocompatible adhesive on the TGFR™ Disposable Ring. This transdermal sensor has a built-in cable that connects to a display monitor.
- The MediBeacon® TGFR™ Disposable Ring is a single use device that is assembled with the MediBeacon® TGFR™ Reusable Sensor and attaches to the patient's skin during a TGFR™ session.
- MediBeacon® TGFR™ Monitor is the display monitor and provides power to the TGFR™ Reusable Sensor, provides the number of uses remaining on the TGFR™ Reusable Sensor, provides the user interface, digitizes the data acquired from the TGFR™ Reusable Sensor, contains the algorithms to run the sensor and convert the output to GFR, and displays the GFR to the clinician and/or caregiver.

Key Characteristics

- Point of Care
- May take 8-24 hours to yield GFR results depending on the patient's renal function
- No blood draws
- IV line insertion required
- No urine collection
- No changes necessary to patients' diet or medications
- Nonradioactive, non-iodinated fluorescent tracer agent
- Limited patient movement allowed for 8-24 hours while the GFR is being assessed.

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

Accuracy

Accuracy was assessed in two different studies. The pivotal study, used as the basis for approval, utilized the MediBeacon® TGFR™ Sensor which is a single use sensor. The bridging study utilized the second-generation sensor, the MediBeacon® TGFR™ Reusable Sensor assembled with the single use MediBeacon® TGFR™ Disposable Ring. The technology principles are the same between the two sensors, but the reusable sensor offers up to 20 uses with cleaning and disinfection required between uses.

A. Average Session GFR with the TGFR™ Sensor (single use) - results comparison with measured GFR results (nGFR in the pivotal trial). The pivotal study outcome was 94% of the Average Session GFR values were within 30% of the measured GFR values (95% Confidence Intervals: 89.4-96.9%).

Single use Sensor – Pivotal Study – 5% Alpha

P30 Value	Upper 95% CI	Lower 95% CI
94.0%	96.9%	89.4%

B. Average Session GFR with the TGFR™ Reusable Sensor - results comparison with measured GFR results (nGFR in the bridging study): The bridging study outcome was 96% of the Average Session GFR values were within 30% of the measured GFR values (97% Confidence Intervals: 87.9-99.3%).

Reusable Sensor – Bridging Study – 3% Alpha

P30 Value	Upper 97% CI	Lower 97% CI
96.0%	99.3%	87.9%

C. Average Session GFR - results comparison with estimated GFR (eGFR) results (using the creatinine-based 2009 CKD-EPI equation):

	Average Session GFR	eGFR*
TGFR™ Sensor (Pivotal Study)		
P30	94.0%	92.9%
95% Confidence Interval	89.4-96.9%	88.2-96.1%
TGFR™ Reusable Sensor (Bridging Study)		
P30	96.0%	90.7%
97% Confidence Interval	87.9-99.3%	80.7-96.5%

*The eGFR results above were obtained via post hoc analysis (which was not the predetermined outcome measure from the studies).

In the pivotal trial with the single use TGFR™ Sensor, 94.0% of the Average Session GFR values obtained using this device were within 30% of the measured GFR values and 92.9% of the eGFR values (creatinine based 2009 CKD- EPI equation) were within 30% of the measured GFR values.

In the bridging study with the TGFR™ Reusable Sensor 96.0% of the tGFR values obtained using this device were within 30% of the measured GFR values and 90.7% of the eGFR values (creatinine based 2009 CKD- EPI equation) were within 30% of the measured GFR values.

The confidence intervals overlap (see table in Section C above).

Clinical Study Performance Results

Pivotal Study

The main clinical study was a global, multicenter, open-label, pivotal trial studying the safety and pharmacokinetics of Lumitrace and the use of the TGFR in subjects with normal and impaired renal function, and with different skin color types, comparing the Average Session GFR value computed from transdermal GFR (tGFR) values to plasma derived indexed GFR (nGFR), measured GFR.

The primary endpoint of the pivotal clinical study was the performance measure of P30 for the Average Session GFR with respect to nGFR, with a lower limit of the 95% confidence interval greater than 85%. This P30 value is the number of measurements of Average Session GFR values that differ by no more than 30% from the measurement of nGFR.

The clinical study endpoints were achieved, and the data can be reviewed in the tables above for the full data set and below for the subgroup populations.

Bridging Study

The bridging study for the TGFR™ Reusable Sensor was a multi-center, open-label, adaptive bridging study comparing the transdermal glomerular filtration rate (tGFR) of subjects with normal and impaired renal function, and with different skin color types, to plasma-derived indexed GFR (nGFR) with Lumitrace® (relmapirazin) injection. After 75 evaluable subjects in the validation cohort was complete, an interim analysis was conducted. To control alpha error in the interim analysis, alpha was lowered from 5% to 3% in the endpoint analysis.

The primary endpoint of the bridging study was the performance measure of P30 for transdermal-derived Average Session GFR with respect to the plasma-derived indexed GFR, with a lower limit of the 97% CI greater than 85%.

The bridging study endpoints were achieved at the interim data analysis, the study closed, and the data can be reviewed in the tables above for the full data set and below for the subgroup populations.

Subgroup Population Results

	Pivotal Study (single use sensor)		Bridging Study (reusable sensor)	
Patient Population	P30 Value TGFR™ Sensor	95% Confidence Intervals TGFR™ Sensor	P30 Value TGFR™ Reusable Sensor	97% Confidence Intervals TGFR™ Reusable Sensor
Stratum 1 (eGFR ≥70 mL/min/1.73m^2)	95.6% N=90	89.0% - 98.8%	95.0% N=40	81.7% - 99.5%
Stratum 2 (eGFR < 70 mL/min/1.73m^2)	92.4% N=92	84.9% - 96.9%	97.1% N=35	83.6% - 100.0%

	Pivotal Study (single use sensor)		Bridging Study (reusable sensor)	
Patient Population	P30 Value TGFR™ Sensor	95% Confidence Intervals TGFR™ Sensor	P30 TGFR™ Reusable Sensor	97% Confidence Intervals TGFR™ Reusable Sensor
FSS Type I-II	96.1% N=77	89.0% - 99.2%	100% N=25	84.5% - 100.0%
FSS Type III-IV	92.8% N=69	83.9% - 97.6%	92.3% N=26	72.9% - 99.3%
FSS Type V-VI	91.7% N=36	77.5% - 98.3%	95.8% N=24	76.9% - 99.9%

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

The following may affect the effectiveness/accuracy of this device:

- Subjects were enrolled across a range of skin tones, but individual skin tones were not powered to provide statistical significance (see subpopulation data above).
- IV fluid bolus administration
- Patient movement during the 8-24 hours that the device takes to produce GFR results.

Product Safety Information

In clinical trials, there were no serious adverse effects or deaths. For patients receiving a 7 ml dose of Lumitrace injection, the most common adverse effects included:

- Injection site extravasation (11/512, 2%)
- Headache (7/512, 1%)
- Hypertension (5/512, 1%)
- Ecchymosis (3/512, 1%)

There are no available data on Lumitrace use during pregnancy to evaluate for a drug associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes.

There are no data on the presence of relmapirazin in human milk, the effects on the breastfed infant or the effects on milk production.

In pregnant rats and rabbits, no evidence of harm to the fetus was observed following intravenous administration of Lumitrace at doses up to 225 and 113 mg/kg/day (highest doses tested), respectively, which correspond to approximately 8 times the MRHD of 260.4 mg/day based on body surface area. Animal reproduction studies are not always predictive of human response.

What are the approved available alternatives?

The most common clinical practice for GFR estimation is to use a clinical laboratory test for creatinine and/or cystatin C levels and an estimation equation.

Precautions:

- A linear regression analysis found that the mean of the difference tGFR - nGFR tended to decrease by -0.37 mL/min/1.73m^2 per year increase in age after adjustment for nGFR, Sex, Race and Fitzpatrick skin scale, which all had insignificant effects. For example, a 10-year increase in age will tend to decrease the difference by 3.7 mL/min/1.73m^2.
- In the study tGFR tended to underestimate nGFR (mean difference -5.3, 95% CI -7.8, -2.9). For example, if the nGFR reports a GFR value of 30 ml/min/1.73m^2, then the tGFR value was on average about 25 ml/min/1.73m^2.
- Not MRI compatible
- Bolus fluid infusions may impact the GFR readings temporarily while the vasculature-tissue equilibrium is reestablished
- High energy electromagnetic and radio frequencies (e.g., cauterizing or electrosurgical equipment) may interfere with system performance

Where can I go for updates?

Clinical practice guidelines and CDC Kidney Disease Surveillance System can be accessed at these websites:

- **KDIGO Guidelines: Guidelines – KDIGO**
- **CDC Kidney Disease Surveillance System: Kidney Disease Surveillance System (cdc.gov)**

Additional information on the MediBeacon Transdermal GFR System is available on the MediBeacon website.

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**

MediBeacon Inc.:
425 N. New Ballas Road, Suite 100
St. Louis, MO 63141

Contact number: +1-800-669-8326

Label Website: IFU.MediBeacon.com

General Information: MediBeacon.com

MediBeacon, the MediBeacon logo, the MB Logo, Lumitrace, the Lumitrace logo, TGFR, and “Life, illuminated.” are trademarks owned by and/or registered to MediBeacon Inc. in the U.S. and/or other countries.

© 2026 MediBeacon Inc. All rights reserved

Report Adverse events, including problems with device performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/) or by calling **1-800-FDA-1088**