



Diagnostic Green

IC-Green® (indocyanine green for injection),
for intravenous or interstitial use

Overview



Company Vision and Strategy

The Diagnostic Green company is the leading provider of trusted high quality fluorescence products for physicians worldwide.

Our Vision

Diagnostic Green was established to provide high quality fluorescence imaging products to physicians worldwide. Our vision is to ensure that fluorescence imaging becomes the standard in tissue visualization worldwide, to help improve clinician outcomes, minimize procedure complications and thereby reduce overall healthcare costs.

We aspire to maintain our global leadership in the manufacture and distribution of ICG Diagnostic Products with guaranteed availability of high quality products – anytime, anywhere.

Diagnostic Green

Core Values

The Diagnostic Green's core values serve as a foundation for the way we conduct business with our **distributors, customers** and **physicians**.



Integrity



Professionalism



Accountability



Teamwork



Excellence



Flexibility

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Company History



1991

Registration of ICG
Diagnostic Product in
Europe



2007

Marketing Authorization for
ICG by the US FDA



2015

Renew Group Private Ltd
acquire both Diagnostic
Green GmbH, and Diagnostic
Green LLC



2016

IC-Flow™ Imaging System
receives CE mark.
VERDYE, new product name for
our ICG in certain territories



2019+

Diagnostic Green's ICG
pharmaceutical product
expands to new territories
worldwide

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IC-Green® (indocyanine green for injection) for intravenous or interstitial use

Diagnostic Green's Indocyanine Green is the leading fluorescence product trusted by physicians worldwide, to guide their treatment procedures, based on fluorescence.

*Indocyanine Green (ICG), is well known and accepted by surgeons worldwide (over 18,000 published articles on use and applications)**


Key Features of ICG

- Safe and well tolerated**
- Excellent safety profile***
- Half-life of 3-4 minutes
- Rapidly bound to plasma protein
- Undergoes no significant extrahepatic or enterohepatic circulation
- Secreted entirely into the bile

*<https://www.ncbi.nlm.nih.gov/pubmed/?term=indocyanine+green>

** <https://radiologykey.com/clinical-applications-of-diagnostic-indocyanine-green-angiography/>

*** <https://www.ncbi.nlm.nih.gov/pubmed/635011>



Approved IC-Green® (indocyanine green for injection) for intravenous or interstitial use*

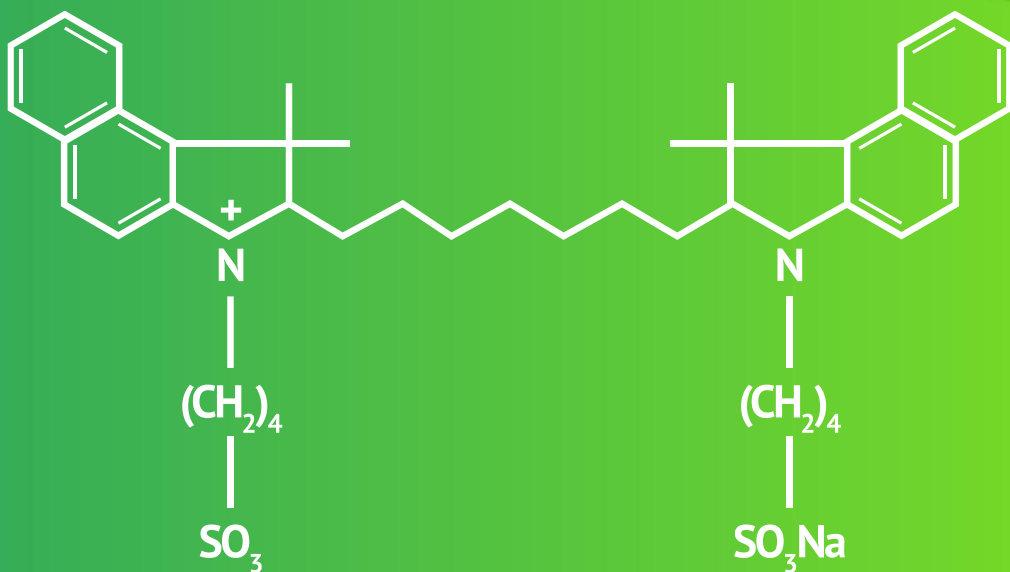
Product Indications

- Fluorescence imaging of vessels (micro- and macro-vasculature), blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures, in adults and pediatric patients aged 1 month and older.
- Fluorescence imaging of extrahepatic biliary ducts in adults and pediatric patients aged 12 years and older.
- Fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer.
- Ophthalmic angiography in adults and pediatric patients

**approved indications in USA. For full prescribing information , go to <https://diagnosticgreen.com/am/package-insert/>*

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Chemical Description



- **Chemical Description:** *Tricarbocyanine Dye*
- **Appearance:** Lypophilized green powder
- **Empirical Formula:** $C_{43}H_{47}N_2NaO_6S_2$

IC-Green® (indocyanine green for injection) for intravenous or interstitial use

How it is Supplied

- **Active Substance:** Indocyanine Green for Injection (lyophilized powder)
- **Package configuration:** available in vial kit of 6 vials of the lyophilized green powder and 6 vials of 10 mL Sterile Water for Injection, USP
- **Vial strength:** 25 mg



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IC-Green® (indocyanine green for injection) for intravenous or interstitial use

Prescription only Medicine (Rx Only)

Indications:

IC-GREEN® is an optical imaging agent indicated for:

- Fluorescence imaging of vessels (micro- and macro-vasculature), blood flow and tissue perfusion before, during and after vascular, gastrointestinal, organ transplant, plastic, micro- and reconstructive surgeries, including general minimally invasive surgical procedures, in adults and pediatric patients aged 1 month and older
- Fluorescence imaging of extrahepatic biliary ducts in adults and pediatric patients aged 12 years and older
- Fluorescence imaging of lymph nodes and lymphatic vessels during lymphatic mapping in adults with cervical and uterine cancer
- Ophthalmic angiography in adults and pediatric patients

To report SUSPECTED ADVERSE REACTIONS

Contact Diagnostic Green LLC (24/7) at 1-844-424-3784 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For full prescribing information, go to <https://diagnosticgreen.com/am/package-insert/>

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Prescription only Medicine (Rx Only)

Dosage and Administration:

- Visualization of vessels, blood flow and tissue perfusion (2.5 mg/mL solution)
 - 1.25 mg to 5 mg by intravenous injection is recommended for a surgical procedure in adults and pediatric patients aged 1 month and older.
 - 3.75 mg to 10 mg by intravenous injection is recommended for visualization of perfusion in extremities through the skin for plastic, micro- and reconstructive surgeries in adults.
 - Additional doses may be administered. Do not exceed a total dose of 2 mg/kg.
- Visualization of extrahepatic biliary ducts in adults and pediatric patients aged 12 years and older (2.5 mg/mL solution)
 - 2.5 mg by intravenous injection at least 45 minutes prior to surgery.
 - Additional doses may be administered. Do not exceed a total dose of 2 mg/kg.
- Lymphatic mapping of cervical and uterine cancer in adults (1.25 mg/mL solution)
 - 5 mg interstitially as four 1 mL injections.
 - See Full Prescribing Information for injection techniques.
- Ophthalmic Angiography
 - Doses up to 40 mg in 2 ml of Sterile Water for Injection by intravenous injection.

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USA and Canada Distributors

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Worldwide

Registration & Distribution

Registered Territories

Argentina, Australia, Austria, Belgium, Canada, Chile, Croatia, Czechia, Denmark, El Salvador, Finland, Germany, Greece, Guatemala, Hungary, Ireland, Israel, Italy, Kuwait, Malta, Mexico, Mongolia, Netherlands, New Zealand, Panama, Poland, Portugal, Romania, Russia, Slovenia, Spain, Sweden, UK, Ukraine, USA



Distribution also available:

Other Territories

As well as the 35 countries where approved, we also supply under exemption to another 45+ territories in Middle East, South East Asia and South America

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