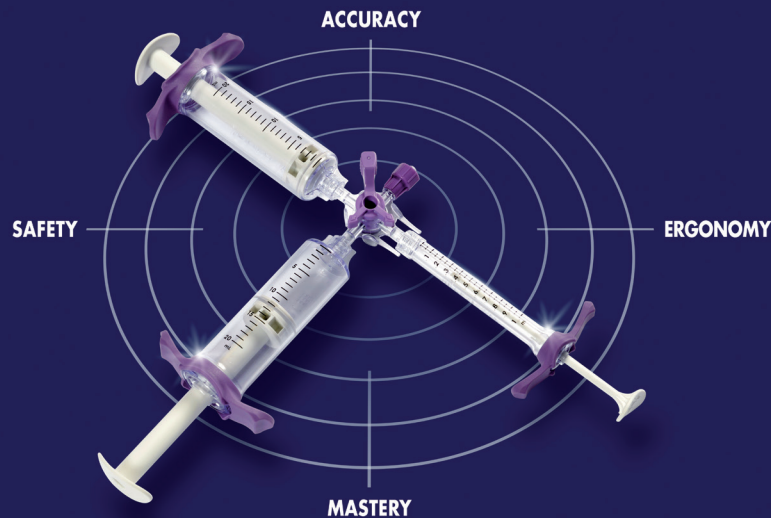


VECTORIO®

Kit for imaging of HCC

Vectorio® efficacy & safety for HCC imaging & delivery



UNBREAKABLE | USER-FRIENDLY | SHARP



Guerbet |

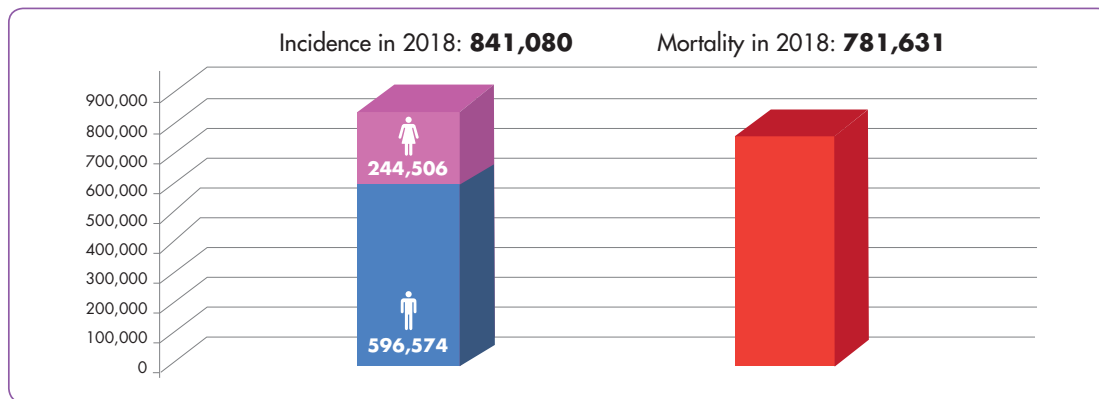


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Primary liver cancer epidemiology

- 841,080 new cancer cases worldwide occurred in 2018⁽¹⁾
- 6th most common cancer and 4th most common cause of death from cancer worldwide⁽¹⁾
- HCC represents more than 90% of primary liver cancers⁽²⁾
- Very poor prognosis

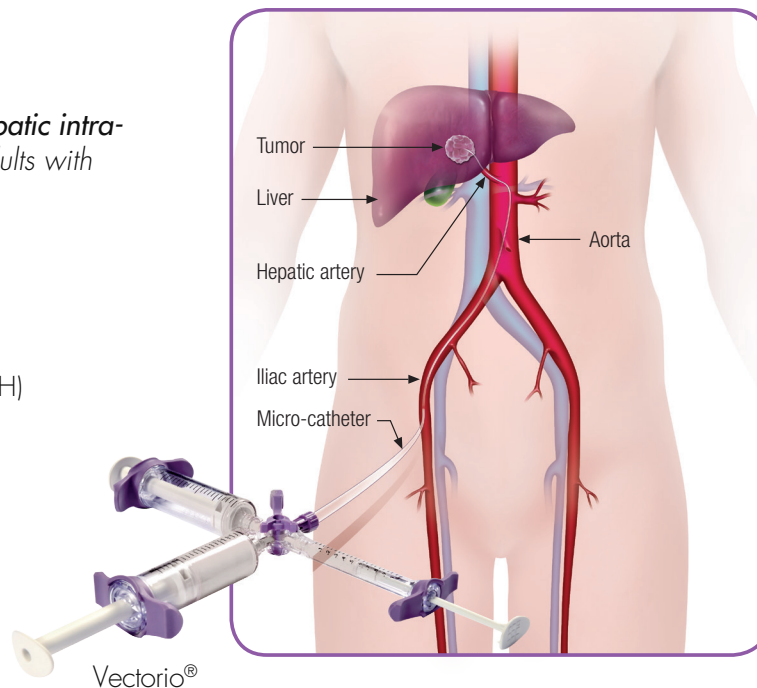


PRIMARY LIVER CANCER – A DEADLY DISEASE

Lipiodol® indication in HCC

*Lipiodol® is indicated for **selective hepatic intra-arterial use for imaging tumors** in adults with known HCC.*

- HCC etiology
 - Hepatitis B & C
 - Prolonged alcohol abuse
 - Non alcoholic steato hepatitis (NASH)

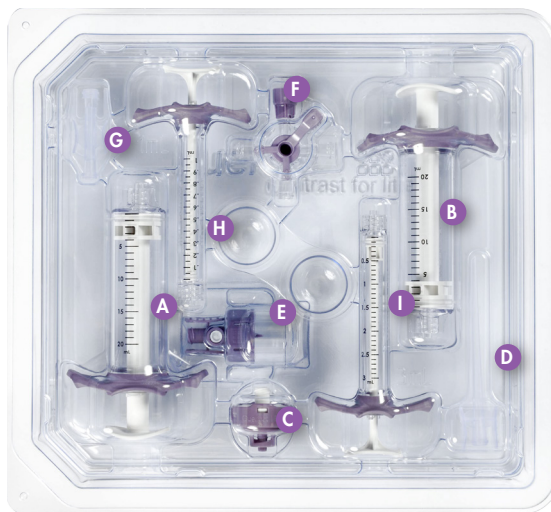


LIPIODOL® – OPTIMAL TUMOR VISUALIZATION IN HCC

VECTORIO® intended use & compounds

LIPIODOL® Resistant Injection kit for HCC Imaging

- Lipiodol® Ultra Fluid – injection should be performed with VECTORIO®
- Function of Vectorio® has been validated for resistance to Lipiodol® up to 24h**



- **A** & **B** 20 mL syringes (x2)
- **C** Particle filter for Lipiodol® Ultra Fluid withdrawal (x1)
- **D** Lipiodol® Ultra Fluid ampule withdrawing straw (x1)
- **E** Lipiodol® Ultra Fluid vial spike*** (x1)
- **F** 3-way stopcock with 4 connections (x1)
- **G** Connector (x1)
- **H** 1 mL injection syringe (x1)
- **I** 3 mL injection syringe (x1)

The system does not contain:

- Lipiodol® Ultra Fluid ampule or vial
- Microcatheter

*Guerbet recommends the use of Vectorio® to inject Lipiodol® **Test report (E17-41) - Verification report of the device's functionality after 24h exposure to Lipiodol®

***Guerbet project under progress



Preparation syringes (20 mL) Design Aim – Making Lipiodol® handling easy & safe



• **Plunger** – Ergonomic convex shape, rotatable, atraumatic for the palm & fingers

• **Backstop (Patented)** – Prevents accidental release & uncontrolled exposure

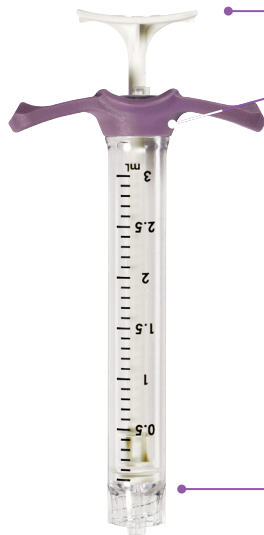
• **Rotary finger support** – Adjustable working position after connection

• **O-ring design** – Sealing function

• **Elimination of the elastic zone** – Tactile feedback improvement, direct transmission of forces from hand to mixture

Injection syringe (1 mL & 3 mL)

Design Aim – Making injection easy & safe



• **Plunger** – Ergonomic design for optimal grip and easy injection

• **Backstop (Patented)** – Prevents accidental release & uncontrolled exposure

• **Rotary finger support** – Obtain more suitable working position

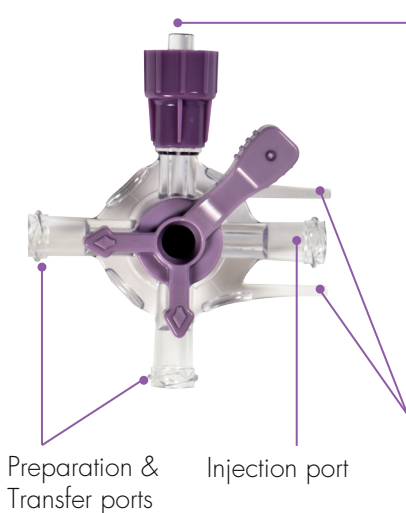
• **O-ring design** – Sealing function

• **Elimination of the elastic zone** – Tactile feedback improvement, direct transmission of forces from hand to emulsion

3-way stopcock with 4 connections – (Patented)

Design Aim – Easy & safe to perform operation

Stopcock maximum pressure: 550 PSI / 38 bar



Microcatheter/patient line connection

- Connects with 2 preparation syringes, Injection syringe & Microcatheter
- The "L" channel & Rotary handle enable to chose which two ports can be connected

**Prepare,
inject and refill
No need to disconnect**

Foolproof Luer lock connection

- Vectorio® 20 mL preparation syringes can't be connected to injection port
- Preparation ports can't communicate with the patient

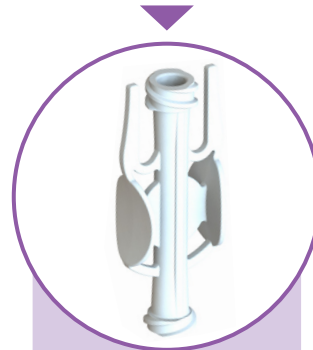
**Particle filter for
withdrawing Lipiodol®**

**Double female
connector**

Design Aim – Easy & safe to perform preparation



1.5µm filter retain glass particles that may be released when breaking ampoule



Transfer contrast agent to the preparation syringe of Vectorio® (If needed)





Lipiodol® Ultra Fluid – preparation for HCC imaging using

STEP I: WITHDRAWING



CONNECTION TO THE STOPCOCK



- Withdraw Lipiodol® Ultra Fluid into the 20 mL preparation syringe

VECTORIO®

STEP II: DILUTION (IF NEEDED)



- Dilution of Lipiodol® with water soluble contrast media by two 20 mL syringes connected to the stopcock

STEP III: INJECTING



- Connect stopcock to the microcatheter
- Lipiodol® Ultra Fluid ready to inject
- Possibility of refill within closed system

**THE PREPARATION SHOULD BE PERFORMED EXTEMPORANEOUSLY
AND INJECTED IMMEDIATELY**

Features & benefits of VECTORIO®

Features

▶ Lipiodol® Resistant & Unbreakable



▶ Ergonomic & User-Friendly

- ✓ Syringe back stop
- ✓ Rotary finger grip
- ✓ Optimized-handling



▶ 3W4P* Stopcock System

- ✓ Unique 3-way
4 Ports stopcock
- ✓ Ports safe-guards
- ✓ Closed system



Benefits

- **Safety** – Closed system to reduce risks of leakage
- **Swiftness** – No devices break & no devices change

- **Safety** – No syringe pull-back & no liquids projection
- **Accuracy** – Easy-to-handle & sharp
- **Swiftness** – Easy-to-inject
- **Convenience** – Ready-to-use

- **Safety** – Reduced risks of infection, air injection, leaks
- **Swiftness** – less connection mistakes
& no disconnection time
- **Convenience** – On-table Refill & optimized
injection control

* 3-way & 4 ports

Bibliography

- (1) WHO , cancer today Liver Source: Globocan 2018, <http://gco.iarc.fr/today/data/factsheets/cancers/11-Liver-fact-sheet.pdf>
- (2) EASL-EORTC Clinical Practice Guidelines: Management of hepatocellular carcinoma. *Journal of Hepatology* 2012; 56: 908–943.

LIPIODOL® ULTRA-FLUID. Composition: Ethyl esters of iodized fatty acids of poppy seed oil 10 mL, corresponding to an iodine content of 480 mg/mL. **Indications (**):** In diagnostic radiology - Hysterosalpingography - Ascending urethrography - Lymphography - Sialography - Fistulography and exploration of abscesses - Exploration of frontal sinuses - Pre and post-operative cholangiography. In interventional radiology - Visualisation and localization (by selective intra-arterial use during CT) of liver lesions in adults with known or suspected hepatocellular carcinoma - Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults - Selective embolization in combination with Histoacryl glue (particularly for arteriovenous malformation or aneurysms) - Selective injections of LIPIODOL ULTRA-FLUID into the hepatic artery for diagnostic purposes where a spiral CT scan is not practical. In endocrinology - Prevention of severe cases of iodine deficiency. **Posology and method of administration (*):** have to be adapted according to the type of examination, the territories explored, the age and weight of the patient. The volume to be administered depends on the particular requirements of the technique and the size of the patient. **Contraindications:** Hypersensitivity to LIPIODOL ULTRA-FLUID - Confirmed hyperthyroidism - Patients with traumatic injuries, recent haemorrhage or bleeding - Hysterosalpingography during pregnancy or acute pelvic inflammation - Bronchography. In interventional radiology (Trans-Arterial Chemo-Embolization), Administration in liver areas with dilated bile ducts unless drainage has been performed. **Special warnings and special precautions for use (*):** There is a risk of hypersensitivity regardless of the dose administered. **Lymphography:** Pulmonary embolism may occur immediately or after few hours to days from inadvertent systemic vascular injection or intravasation of LIPIODOL ULTRA-FLUID: Perform radiological monitoring during LIPIODOL ULTRA-FLUID injection and avoid use in patients with severely impaired lung function, cardiorespiratory failure or right-sided cardiac overload. **Hypersensitivity:** all iodinated contrast agents can lead to minor or major hypersensitivity reactions, which can be life-threatening. These hypersensitivity reactions are of an allergic nature (known as anaphylactic reactions if they are serious) or a non-allergic nature. They can be immediate (occurring within 60 min) or delayed (not occurring until up to 7 days later). Anaphylactic reactions are immediate and can be fatal. They are dose-independent, can occur right from the first administration of the product, and are often unpredictable: avoid use in patients with a history of sensitivity to other iodinated contrast agents, bronchial asthma or allergic disorders because of an increased risk of a hypersensitivity reaction to LIPIODOL ULTRA-FLUID. **Thyroid:** can cause hyperthyroidism in predisposed patients. Lymphography saturates the thyroid with iodine for several months and thyroid exploration should be performed before radiological examination. **Chemo-Embolization:** Trans-Arterial Chemo-Embolization is not recommended in patients with decompensated liver cirrhosis (Child-Pugh ≥ 8), advanced liver dysfunction, macroscopic invasion and/or extra-hepatic spread of the tumour. Renal insufficiency must be prevented by correct rehydration before and after the procedure. Oesophageal varices must be carefully monitored. Hepatic intra-arterial treatment can progressively cause an irreversible liver insufficiency in patients with serious liver malfunction and/or undergoing close multiple sessions. The risk of superinfection in the treated area is normally prevented by administration of antibiotics. **Embolization with glue:** An early polymerisation reaction may exceptionally occur between LIPIODOL ULTRA-FLUID and certain surgical glues, or even certain batches of glue. Before using new batches of LIPIODOL ULTRA-FLUID or surgical glue, the compatibility of LIPIODOL ULTRA-FLUID and the glue must be tested in vitro. **Interaction with other medicinal products and other forms of interaction (*):** Metformin, Beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin-receptor antagonists, Diuretics, Interleukin II. **Fertility, pregnancy and lactation (*):** LIPIODOL ULTRA-FLUID must only be used in pregnant women if absolutely necessary and under strict medical supervision. Breastfeeding should be discontinued if LIPIODOL ULTRA-FLUID must be used. **Effects on ability to drive and use machines:** The effects on ability to drive and to use machines have not been investigated. **Undesirable effects (*):** Most adverse effects are dose-related and dosage should therefore be kept as low as possible: hypersensitivity, anaphylactic reaction, anaphylactoid reaction, vomiting, diarrhea, nausea, fever, pain, dyspnea, cough, hypothyroidism, hyperthyroidism, thyroiditis, pulmonary embolism, cerebral embolism, retinal vein thrombosis, lymphoedema aggravation, hepatic vein thrombosis, granuloma. **Overdose (*):** The total dose of LIPIODOL ULTRA-FLUID administered must not exceed 20 mL - **Pharmacodynamic properties (*):** Pharmacotherapeutic group: X-ray contrast media, iodinated; ATC code: V08A D01. Water-insoluble iodinated contrast medium. **Presentation (**):** 10 mL glass ampoule. **Marketing authorization holder (*):** Guerbet - BP 57400 - F-95943 Roissy CdG cedex - FRANCE. Information: tel: 33 (0) 1 45 91 50 00. **Revision:** April 24th, 2018.

(*) For complete information please refer to the local Summary of Product Characteristics

(**) Indications, volumes and presentations may differ from country to country.

Reporting of suspected adverse reactions is important as it helps to continuously assess the benefit-risk balance. Therefore, Guerbet encourages you to report any adverse reactions to your health authorities or to our local Guerbet representative.

VECTORIO® - SET002 is a medical device of Class Is (CE 0459) intended to be used by healthcare professionals only. Manufacturer: Medex, a Guerbet Group company. **Intended use: Injection kit for imaging of liver tumors in adults with known hepatocellular carcinoma (HCC) during interventional radiology procedures.**

For complete information please refer to country's local Package Information Leaflet & Vectorio® - SET002 Instruction For Use (IFU).

Local registration of Vectorio® - SET002 in progress

Countries in which HCC imaging indication is registered: Canada, Germany, United States of America

For a copy of the SPC/ IFU, please contact a member of Guerbet.





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