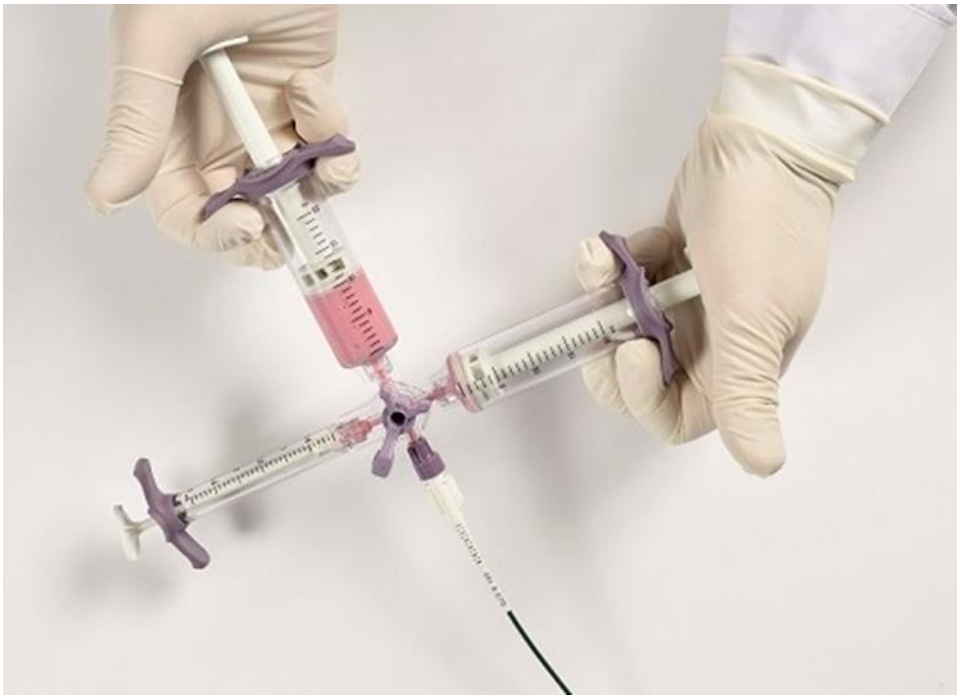
Press release

Vectorio® Registration in India, An Innovative Medical Device for cTACE Procedures

Villepinte (France) – December 3th, 2019 - 06:00pm - Guerbet (GBT) announces that the Ministry of Health & Family Welfare delivered registration for its innovative conventional Trans-Arterial Chemo-Embolization (cTACE) mixing and injection system, Vectorio®, in India.



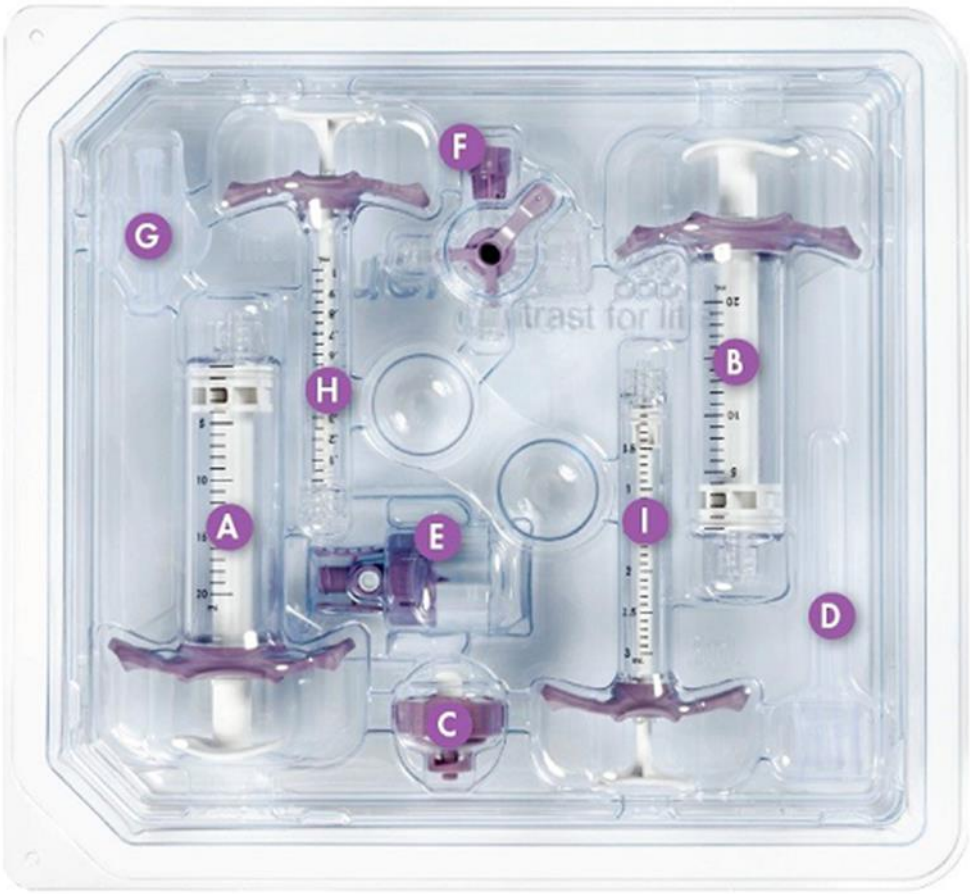
Vectorio® is a set of Lipiodol® resistant medical devices (1) including syringes, patented stopcock and sampling devices. Vectorio® is dedicated for mixing and delivering Lipiodol® Ultra Fluid & anticancer drugs during cTACE procedure in adults with known, intermediate-stage hepatocellular carcinoma (HCC).

HCC is the most common primary liver cancer and is the fourth biggest cause of death due to cancer worldwide (2).

This medical device offers multiple advantages for healthcare professionals:

- 24 hours Lipiodol® Ultra Fluid resistance [1].
- Patented 3-way stopcock with 4 connections offering possibility of "On-table mixing" (interventional radiologists have the possibility of remixing without disconnection from the micro-catheter, thus maximizing the safety during the intervention).
- Ready-to-use set: all devices in one set.
- User-friendly: Ergonomic and quick device set-up, improving cTACE procedures for physicians.

"*Vectorio® has been developed in collaboration with international interventional radiologists to match their medical needs for an accurate, user-friendly and safe solution during cTACE procedure. Vectorio® has been developed to answer the request of standardization to cTACE procedures by physicians,*" said Philippe Havard, Global Head of Marketing for Interventional Imaging - HCC and VAE



A & B 20 mL mixing syringes (x2)
C Particle filter for Lipiodol® Ultra Fluid withdrawal (x1)
D Lipiodol® Ultra Fluid ampoule sampling 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)

Designed and manufactured in France, Vectorio® 's commercial launch started in September 2017 in European countries. Today, Vectorio® is registered in 20 countries over the world [3]. Vectorio® registration program is running for all countries where Lipiodol® Ultra Fluid is indicated for cTACE [4].

References

(1) Test report (E17-41) – Verification report of the device's functionality after 24h exposure to Lipiodol

(2) WHO – Globocan 2018 (IARC) Global Cancer Observatory.

(3) Countries in which Vectorio® is registered for cTACE: EMEA (Austria, Belgium, Czech Republic, Denmark, France, Hungary, Ireland, Luxembourg, Portugal, Switzerland, The Netherlands, Turkey), Americas (Argentina, Brazil, Mexico, Peru), Asia-Pacific (Hong Kong, India, New Zealand, South Korea, Thailand, Vietnam). Vectorio® is also registered for HCC imaging in Germany.

(4) Countries in which cTACE indication is registered for Lipiodol® Ultra Fluid: EMEA (Austria, Belgium, Czech Republic, Denmark, France, Hungary, Iran, Ireland, Luxembourg, Portugal, Switzerland, The Netherlands, Tunisia, Turkey), Americas (Argentina, Brazil, Mexico, Peru), Asia-Pacific (Cambodia, Hong Kong, India, Mongolia, New Zealand, Philippines, South Korea, Sri Lanka, Taiwan, Thailand, Vietnam). Countries in which HCC imaging indication is registered for Lipiodol® Ultra Fluid: Canada, Germany, United States of America.

About Vectorio®

Vectorio® is a sterile medical device set of class Is (CE 0459) intended to be used by healthcare professionals only. It is a Lipiodol® resistant mixing and injection system for Trans-Arterial Chemo-Embolization (cTACE) procedures.
For complete information please refer to country's local Package Information Leaflet & Vectorio® Instruction For Use (IFU). Vectorio® is manufactured by Medex, a Guerbet group company.

About Lipiodol® Ultra-Fluid

Lipiodol® Ultra-Fluid (ethyl esters of iodized fatty acids of poppyseed oil) was initially developed for diagnostic radiology in indications including liver lesion diagnosis, lymphography and hysterosalpingography, and then used in interventional radiology for conventional transarterial chemo-embolization (cTACE) procedures of multinodular hepatocellular carcinoma, where Lipiodol® Ultra-Fluid was used as a procedure visualizer (contrast agent), a drug vehicle (drug carrier), and an embolic. The approved indications for Lipiodol® Ultra-Fluid may vary according to countries. Please refer to local SmPC for further information.

About cTACE

Conventional transarterial chemo-embolization (cTACE) is a minimally invasive procedure which consists of mixing Lipiodol® Ultra-Fluid with an anticancer drug and injecting this treatment trans-arterially in the liver as a loco-regional targeted chemotherapy, in which Lipiodol® Ultra-Fluid acts as a contrast agent, a drug eluting vehicle and a dual arterio-portal transient embolic [2]. cTACE was first performed in Japan in 1982 and then used effectively throughout Asia, Europe, the Middle East and Africa, as well as North America.

Press release

About Guerbet

Guerbet is a pioneer in the contrast-agent field, with more than 90 years' experience, and is a leader in medical imaging worldwide. It offers a comprehensive range of pharmaceutical products, medical devices and services for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. With 8% of revenue dedicated to R&D and more than 200 employees distributed amongst its four centers in France, Israel and the United States, Guerbet is a substantial investor in research and innovation. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €790 million in revenue in 2018. For more information about Guerbet, please visit www.guerbet.com.

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