OptiRAY

ioversol

In Pre-Filled Syringe

Reduced risk

Patient safety
improvement

Guerbet
Contrast for Life

The risks of broken glass vials

A research conducted by ASRT (American Society of Radiologic Technologists) in order to assess workplace safety issues surrounding the administration of CM, concluded that 25% of the workplace-related accidents involve broken glass vials of contrast media. [1]

In the same research, respondents agreed that glass bottles could be responsible for sharps risks, ergonomic risks or latex allergies and that they add difficulties in complying with work safety guidelines.

Manual filling of syringes: a possible source of infection amongst healthcare professionals [2]

Risk of contamination and patient infection is associated to:

- Contamination of contrast media syringes and tubes [3]
- Use of residual volume of contrast media for subsequent injection [4]

Up to 10 days
additional days of hospitalization [2]

$35.367
mean cost [2]

Between $3,2 to $4,2 billions
annual cost for the health system in USA [2]

Note: the numbers mentioned above are related to the impacts of Hospital MRSA Infections.

1. American Society of Radiologic Technologists Education and Research Foundation. Contrast administration safety survey. Albuquerque, NM: American Society of Radiologic Technologists: 2006. https://www.asrt.org/docs/default-source/research/contrastadminsafetyreport.pdf?sfvrsn=2
2. APIC. Guide to the elimination of methicillin-resistant Staphylococcus aureus (MRSA) transmission in hospital settings, 2nd edition. 2010
3. Panella H, et al. Transmission of hepatitis C virus during computed tomography scanning with contrast. Emerg Infect Dis 2008;14:333-6
4. Vogl TJ et al An observational study to evaluate the efficiency and safety of ioversol pre-filled syringes compared with ioversol bottles in contrast-enhancedexaminations. Acta Radiol. 2012: 1–7

Single-use: a key option in the routine clinical use*[5]

- To allow **time-efficient assembly of injection systems** instead of refilling a syringe for each patient
- To help **prevent microbiologic contamination** in clinical routine, especially in the care of immunocompromised patients

Contrast media in pre-filled syringes: a pratical way to ensure safety

A study was performed simulating microbiologic contamination of the contrast agent and injection syringes under normal hygienic condition and intensive hygienic prevention **[6]

Only a single use of an injection syringe for one patient provides hygienic conditions that ensure the sterility of a CT injection system [6]

5. Buerke et al, Microbiologic Contamination and Time Efficiency of Use of Automatic MDCT Injectors With Prefilled Syringes: Results of a Clinical Investigation. AJR 2010; 194:299–303

* Methodology: each simulation experiment, under normal hygienic conditions and intensive hygienic prevention, was performed over 8 consecutive days to achieve a valid database of 17 samples per day (n = 136). A total of 272 injections procedures were simulated.

6. Buerke et al, Microbiologic Contamination of Automatic Injectors at MDCT: Experimental and Clinical Investigations. AJR 2008; 191:W283–W287

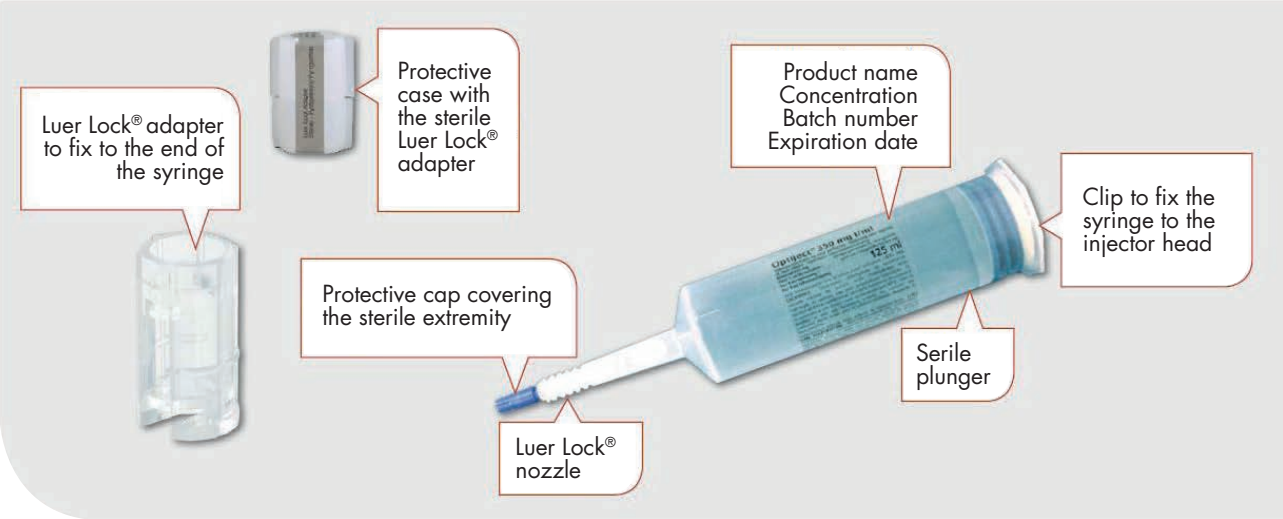
** Methodology: first criteria was to evaluate bacterial contamination of the palms of staff and work surfaces in the CT unit, from technical (n = 20), medical staff (n = 10) and surfaces (n = 25). A total of 110 imprints (55 on day 1, 55 on day 2) were analysed. Second criteria was to evaluate time efficiency, assembly of the automatic injection system for the single-use protocol (n = 60) and for the multiple-use protocol (n = 60) was timed.

OptiRAY® in pre-filled syringes not only minimizes the risk of contamination…

Single-use ioversol pre-filled syringes may be associated with potentially **lower risk of contamination** (than glass vials) [4]

… but also brings additional benefits such as:

- Help on the reduction of crossed-infection or patient administration errors [2,7]
- Reduce healthcare professionals exposition to risks such as broken glass or needles [8]
- Offer a sterile and closed system
- Help on the time management [9]
- Allow easy manipulation [7,9]

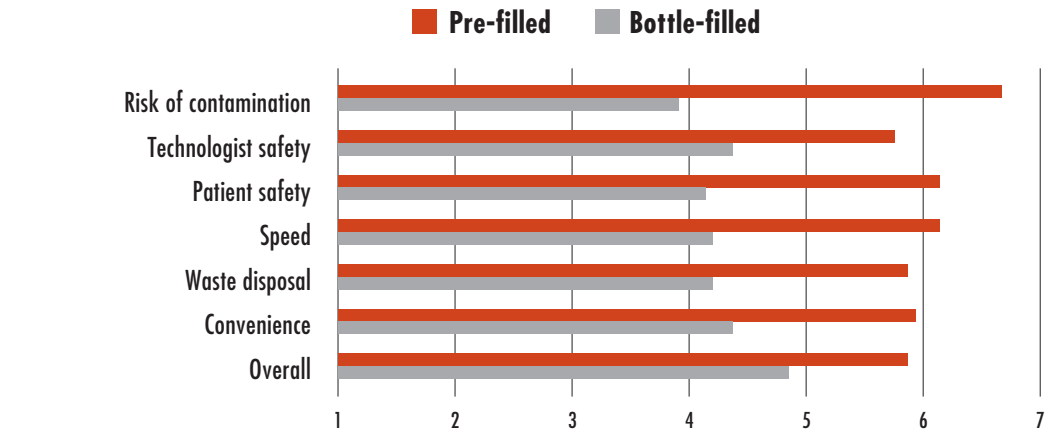


2. American Society of Radiologic Technologists Education and Research Foundation. Contrast administration safety survey. Albuquerque, NM: American Society of Radiologic Technologists: 2006. https://www.asrt.org/docs/default-source/research/contrastadminsafetyreport.pdf?sfvrsn=2
4. Vogl TJ et al An observational study to evaluate the efficiency and safety of ioversol pre-filled syringes compared with ioversol bottles in contrast-enhancedexaminations. Acta Radiol. 2012: 1–7
7. Pichler W et al. Hygiene-related considerations for examinations conducted with contrast media. Wiener Klinisches Magazin; March 2009:36-39
8. Mongin-Bulewski C. Recommendations on the use of contrast media prefilled syringes in radiology: a roundtable discussion. Hospital Pharmacy Europe. May/June 2007, No 32:27-30. http://www.hospitalpharmacyeurope.com/featured-articles/recommendations-use-contrast-media-prefilled-syringes-radiology-roundtable-discuss
9. Lafuma A et al. Comparison on the time to prepare contrast media injection in CT scan exam with prefilled syringes and bottles in 7 European countries. Value Health. The Journal of the International Society for Pharmacoeconomics and Outcomes Reasearch. 2009; 12(7):pA254. http://dx.doi.org/10.1016/S1098-3015(10)74244-3

Radiographers prefer pre-filled syringes [10]

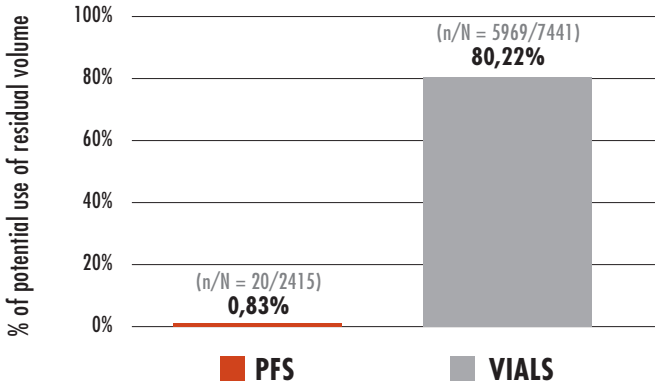
89% percent of the radiographers indicated that they were satisfied with pre-filled syringes and **64%** were very or **extremely satisfied**.

Technologist ratings of pre-filled syringes versus bottle-filled cartridges (N=29)



1=extremely dissatisfied
2=very dissatisfied
3=somewhat dissatisfied
4=neutral
5=somewhat satisfied
6=very satisfied
7=extremely satisfied.

The potential use* of residual volume is lower with PFS than bottles [6]



The Increased Relative Risk of continued use for bottles vs. prefilled syringes is 96.9 (95% confidence interval [CI]: 62.6-149.9) [6]

The volume of **OptiRAY®** in pre-filled syringes was enough to accommodate 98% of the CT examinations in this study [4]

OptiRAY® in pre-filled syringes is associated with a residual volume lower than 25 mL in 62.65% which is essential to discourage re-use [4]

* Based on direct question asked to investigators at the end of examination

4. Vogl TJ et al An observational study to evaluate the efficiency and safety of ioversol pre-filled syringes compared with ioversol bottles in contrast-enhancedexaminations. Acta Radiol. 2012: 1–7

10. Enterline D. Examining pre-filled syringes versus bottle-filled cartridges for contrast-enhanced CT examination. A multicenter time-efficiency trial. Decision in Imaging Economics. 2003. http://151.236.43.146/images/stories/pdf/pressroom/TimeMotion.pdf

Our solutions to improve your single-use daily practice

OptiRAY® in Pre-Filled Syringes (PFS)

Our contrast media that optimizes image quality, patient comfort and clinician confidence in its pre-filled syringe presentation

- Safe[11] and hygienic
- Quick and easy workflow
- Exclusive for single use (one patient)
- No glass and no needle

4 different concentrations: 240, 300, 320 and 350 mg I/mL
Available in 50 to 125 mL volumes*

OR

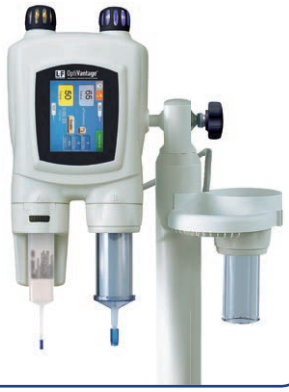
OptiVantage®

DUAL-HEAD CT CONTRAST DELIVERY SYSTEM

For ultimate patient side safety and control

- Fully programmable touchscreen powerhead and control room console
- Dual-head versatility supports both prefilled and disposable syringes
- Patency Check™, Timing bolus™, Scan delay and inject delay
- Tilt enable to help reduce the risk of air injection
- Simultaneous injection as standard
- Interfacing available for a wide selection of scanner manufacturers (ask for details)
- Optional OptiBolus™ for dynamic scanning procedures

Disposables
Syringe Multipack - contains 1 x 200 mL Syringe, filling tube and Y-line



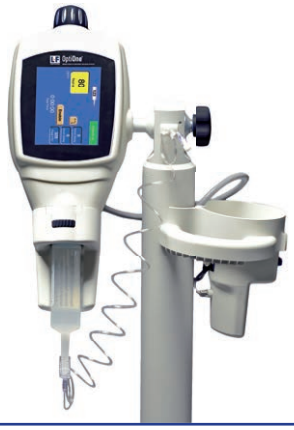
OptiOne®

SINGLE-HEAD CT CONTRAST DELIVERY SYSTEM

All the features of the OptiVantage®, in a cost effective, single-head solution

- Intuitive and easy to use
- Fully programmable powerhead with intuitive touchscreen
- Supports either prefilled or disposable syringes
- Optibolus™ «ready»
- Timing bolus™, Scan delay and inject delay as standard

Disposables
150 cm Coiled Extension Tubing



*Not all presentations may be available in your country. Please check with your local Guerbet representative for more information.

11. Gomi T. et al., Are there any differences in acute adverse reactions among five low-osmolar non-ionic contrast media? Eur. Radiol., 2010; 20: 1631-1635

Prescribing information

Please refer to the Summary of Product Characteristics before prescribing. **Composition:** OPTIRAY™ 240 Ioversol, 509 mg/ml, which is equivalent to 240 mg/ ml of elemental iodine. OPTIRAY™ 300 Ioversol, 636 mg/ml, which is equivalent to 300 mg/ml of elemental iodine. OPTIRAY™ Ioversol, 678 mg/ml, which is equivalent to 320 mg/ml of elemental iodine. OPTIRAY™ Ioversol, 741 mg/ml, which is equivalent to 350 mg/ml of elemental iodine. **Indications:** OPTIRAY™ non-ionic X-ray contrast medium for injection or infusion. Depending on the preparation, it is indicated for use in cerebral, coronary, peripheral, visceral and renal angiography, in aortography, left ventriculography, venography, intravenous excretory urography and computed tomography (CT) of the head and body. Except for OPTIRAY™ 300, safety and effectiveness of OPTIRAY™ in children has not yet been established. **Posology and Method of Administration:** The dosage may vary between 1 ml and 150 ml, maximum total dose 250 ml or less. Please refer to the Summary of Product Characteristics for the recommended dosage schedule. **Contraindications:** Proven hypersensitivity to iodine-containing contrast media. Manifest hyperthyroidism. **Special Warnings and Precautions for Use:** As with all other X-ray contrast media, OPTIRAY™ may cause anaphylaxis or other manifestations of pseudo-allergic intolerance reactions, e.g. nausea, vomiting, dyspnoea, erythema, urticaria and hypotension. Pretesting cannot be relied upon to predict severe reactions. The thorough assessment of the medical history of the specific patient may be more accurate in predicting potential adverse reactions. A positive history of allergy is not a contraindication, but does require caution. Diagnostic procedures, which involve the use of iodinated intravascular contrast agents, should be performed under the direction of personnel skilled and experienced in the particular procedure to be performed. Serious or fatal reactions have been associated with the administration of iodinated X-ray contrast media. A fully equipped emergency cart, or equivalent supplies and equipment, and personnel competent in recognising and treating adverse reactions of all types should always be available for at least 30 to 60 minutes after administration. Patients with congestive heart failure should be observed for several hours following the procedure to detect delayed haemodynamic disturbances, which may be associated with a transitory increase in the circulating osmotic load. All other patients should be observed for at least one hour after the application, as it has been reported that most of the adverse events occur in this period. The patient should also be informed that allergic reactions may develop up to several days post administration; in such case, a physician should be consulted immediately. Caution must be exercised in patients with severely impaired renal function, combined renal and hepatic disease, anuria, diabetes mellitus, homozygotic sickle cell disease, or monoclonal gammopathy (multiple myeloma, Waldenströms macro-globulinaemia), particularly when large doses are administered. Serious renal effects, including acute renal failure, may occur in these patients. Preparatory dehydration is dangerous and may contribute to acute renal failure. Iodine-containing contrast media may also be hazardous in patients with hyperthyroidism or with autonomous areas of the thyroid gland. In patients with phaeochromocytoma a premedication with alpha-blockers is advisable when the contrast medium is administered intravascularly due to the risk of a hypertensive crisis. Serious neurologic events have been observed following direct injection into cerebral arteries or vessels supplying the spinal cord, or in angiocardiography due to inadvertent filling of the carotids. General anaesthesia may be indicated in selected patients. However, a higher incidence of adverse reactions has been reported in these patients, probably due to the hypotensive effect of the anaesthetic. In angiographic procedures, the possibility of dislodging plaque or damaging or perforating the vessel wall should be considered during catheter manipulation and contrast medium injection. In patients with advanced atherosclerosis, serious hypertension, cardiac decompensation, senility, preceding cerebral thrombosis or embolism, special caution should be exercised. Cardiovascular reactions as bradycardia, rising or falling of blood pressure may occur more often. Angiography should be avoided whenever possible in patients with homocystinuria due to an increased risk of thrombosis and embolism. Optiray™ should be injected with caution to avoid perivascular application. However, significant extravasation of Optiray™ may occur especially during the use of power injectors. Generally, it is tolerated without substantial tissue injury applying conservative treatment. However, serious tissue damage (e.g. ulceration) has been reported in isolated cases requiring surgical treatment. **For interactions and specific warnings**, please refer to summary of product characteristics. **Summary of safety profile:** Adverse reactions following the use of Optiray formulations are generally independent of the dose administered. Usually, they are mild to moderate, of short duration and resolve spontaneously (without treatment). However, even mild adverse reactions may be the first indication of a serious, generalized reaction that can occur rarely after iodinated contrast media. Such serious reactions may be life-threatening and fatal, and usually affect the cardiovascular system. Most adverse drug reactions to Optiray formulations occur within minutes after administration, however contrast related hypersensitivity reactions may occur with a delay of some hours up to several days. **Adverse reactions may be classified as follows:** Hypersensitivity or anaphylactoid reactions are mostly mild to moderate with symptoms like rash, pruritus, urticaria and rhinitis. However, serious reactions may occur. Serious anaphylactic reactions generally affect the cardiovascular and respiratory system. These may be life-threatening and include anaphylactic shock, cardiac and respiratory arrest, or pulmonary oedema. Fatal cases were reported. Patients with a history of allergic reactions are at increased risk of developing a hypersensitivity reaction. Other type 1 (immediate) reactions include symptoms like nausea and vomiting, skin rashes, dyspnoea, rhinitis, paraesthesia or hypotension. Vasovagal reactions e.g. dizziness or syncope which may be caused either by the contrast medium, or by the procedure. Cardiologic side effects during cardiac catheterisation e.g. angina pectoris, ECG changes, cardiac arrhythmias, conductivity disorders, as well as coronary spasm and thrombosis. Such reactions are very rare and may be caused by the contrast medium or by the procedure. Nephrotoxic reactions in patients with pre-existing renal damage or renal vasopathy, e.g. decrease in renal function with creatinine elevation. These adverse effects are transient in the majority of cases. In single cases, acute renal failure has been observed. Neurotoxic reactions after intra-arterial injection of the contrast medium e.g. visual disorders, disorientation, paralysis, convulsions, or fits. These symptoms are generally transient and abate spontaneously within several hours or days. Patients with pre-existing damage of the blood-brain barrier are at increased risk of developing neurotoxic reactions. Local reactions at the injection site may occur in very rare cases and include rashes, swelling, inflammation and oedema. Such reactions occur probably in most cases due to extravasation of the contrast agent. Extended paravasation may necessitate surgical treatment. Extravasation can cause serious tissue reactions including blistering and skin exfoliation, the extent of which is dependent on the amount and strength of the contrast solution in the tissues.

Marketing Authorization Information: The marketing authorization holder, number and date of approval may be differ from one country to another. Volume, presentation and indication may also differ.
For your specific information, please contact your local Guerbet representative.

Date of (partial) revision of the text: March 2016

Injectors and disposables: These products are medical devices intended for use by medical imaging and diagnostic health professionals, for injection of contrast media and saline solutions during a CT exam. For complete information about precautions and optimal usage conditions for these medical devices, we recommend consulting the instructions notice/user's manual.
OptiOne®, OptiVantage®: Class IIb – Disposables: Class IIa – CE0123 – Manufacturer: Liebel-Flarsheim Company LLC - 2111 East Galbraith Road, Cincinnati, OH 45237, USA.

www.guerbet.com

@GuerbetGroup

P17 215 CPR: June 2017 - Photos: Guerbet, annapurna8000

Guerbet