TECHNICAL SHEET

FastLoad™ MR Syringe Pack (Ref. 017348)
FastLoad™ MR Single Syringe Pack (Ref. 640365)
FastLoad™ MR Syringe Pack DCV (Ref. 017356)

Revision 04

March 13, 2019

CE 2797

STERILE	EO

MDD 93/42/EEC, Class IIa

Non-toxic
Non-pyrogenic
Contains phthalates
Latex free

Manufacturer:
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FastLoad™ MR Syringe Pack

FastLoad™ MR Syringe Pack (DCV)

FastLoad™ MR Single Syringe Pack

1 Description

This device is a disposable syringe kit designed for use with EmpowerMR® Injector Systems.

FastLoad™ MR Syringe Pack (with or without DCV)
This kit contains:

- (2) 100 mL syringes,
- (1) 96" connecting Y tube with (1) dual check valve (reference: 017356) OR (2) check valves (reference 017348). Both connecting Y tube variants include (2) non-seize luers.
- (1) Large spike for saline bags and (1) small spike for contrast bottles.

The syringe body is a translucent cylinder having its open end connected to the Empower injector pump via the wiper assembly. The spikes are used to fill the angiographic syringe with either contrast or saline.

FastLoad™ MR Single Syringe Pack
The Single Kit composition and design is based on the FastLoad™ MR Syringe Pack and we removed 1 syringe in order to adapt the kit to the use of the Pre-Filled Syringe adaptors. This is a variant to the existing FastLoad™ MR Syringe Pack.

This kit contains:

- (1) 100ml Syringes,
- (1) 96" connecting tube with (1) check valve and (2) non-seize luers,
- (1) large spike for saline bags.

The syringe body is a translucent cylinder having its open end connected to the Empower injector pump via the wiper assembly. The spike is used to fill the angiographic syringe with either saline.

The maximum operating pressure is 300 psi ~ 2069 kPa.

2 Intended use

The FastLoad MR dual syringe kit is intended to intravenously facilitate the administration of contrast media and flushing solutions into the human vascular systems.

The FastLoad MR single syringe kit is intended to intravenously facilitate the administration of flushing solutions into the human vascular systems. This version has to be used only with Pre Filled Syringe adaptors.

3 Usage Lifetime

Single use only (do not re-use). Re-use may result in cross contamination, risk of infection or device malfunction, for example, air ingress, leaks, or reduced performance.

4 Packaging

Both products are individually packaged in a single sterile medical grade blister. Boxes of 50 pieces.

5 Sterilization

The sterilization process is performed by Ethylene oxide. Sterilization has undergone validation according to EN ISO 11135 standard to reach the sterility assurance level (SAL) 10^{-6}.
The sterility is guaranteed for 3 years (See below). The product cannot be re-sterilized.

6 Quality controls of components and finished products

The device meets the principle requirements and is in conformity with the relevant sections of the applicable harmonized EC standards and other normative documents (MDD 93/42/EEC and applicable recognized standards). Finished devices are applied visual, dimensional and physical tests, following the internal quality procedures.
Sterile finished products are subject to tests of sterility, apyrogenicity, chemical toxicity, residual ethylene oxide following the ISO 10993-7 standard and biocompatibility according to the other ISO 10993 standards.

7 Manufacturing and conformity

This device is produced following the "good manufacturing" norms. Bracco Injeneering maintains a Quality Management System following the EN ISO 13485 standard. The device is in conformity with the MDD 93/42/CEE Directive and its transposition into national laws of Bracco Injeneering authorized European countries.

8 Classification

This medical device is classified "class IIa", and is CE marked following the MDD 93/42/CEE (Annex 2.3 full quality assurance).

9 Waste disposal

Follow specific laws in terms of hospital waste materials.

10 Shelf life

The device is validated for a shelf life is of 36 months (3 years) from the manufacturing date. The expiry date is indicated on every single packaging as well as boxes packaging.

11 Age stability of the device

The medical device is designed and validated to maintain all its chemical, biological and physical characteristics during its entire shelf life, provided it is stored and moved following the indications mentioned herein.