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Declaration of Conformity
According to article 12, medical device directive 93/42/EEC

To whom it may concern:

Shenzhen Maiwei Biotech Co., Ltd. hereby declares that the multi-patient syringe set (Mset) and safety tube (Stube) can be safely used for contrast enhanced CT procedure in combination with high pressure injectors of the following brands: Medrad, Mallinckrodt, Liebel-Flarsheim, Nemoto, Medtron, Imaxeon and EZEM. We are liable for damages to the injector caused by our products. The following items are produced by Shenzhen Maiwei Biotech Co., Ltd., as a manufacturer within the meaning of Directive 93/42/EEC and are validated for the use of a maximum time period of 12 hours:

12hrs dual tubing system (Mtrans)

D1L005, D1L010, D1L006, D1L011

Dual Mset (12hrs syringes in conjunction with dual Mtrans)

A03105, B04105, C07105, D02105, E03105, F02105

This 12 hours validation requires the use of above products in combination with one of the following single-use patient lines with non return check valve(s):

Safety tubes with 2 checkvalves

S0L010, S0L012, S0L014, S0L020, S0L021, S0L022, S0L024, S0L026, S0L040, S0L042, S0L044, S0L153

The hygienic safety from the Mset, Mtrans and Stube were tested as part of bacteriological and virological studies for no more than 12 Hours usage in

Signature: *Woody Chen*
Name: Woody Chen
Title: General Manager



Features:



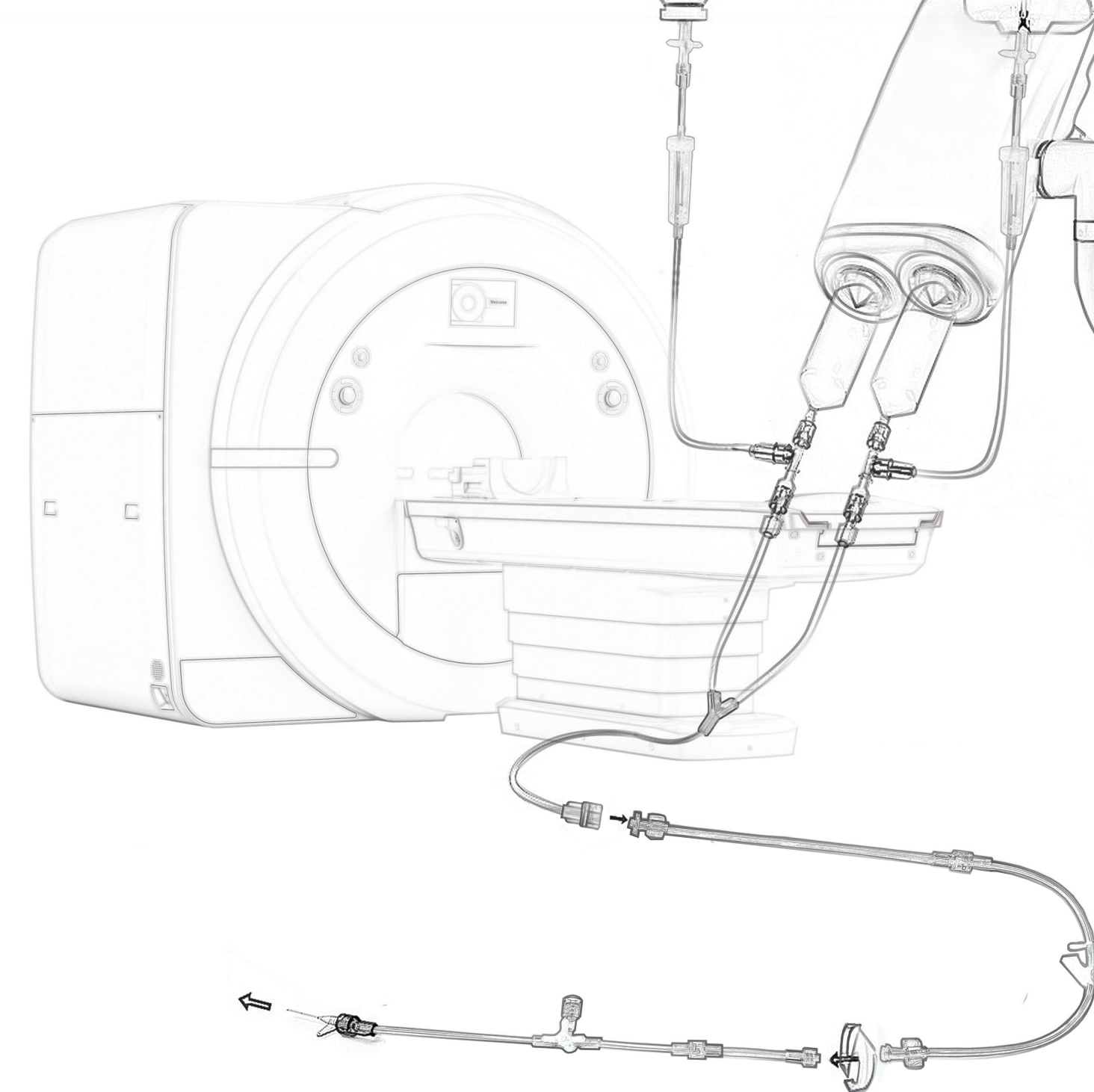
Cost saving
The system allows the syringes and 12hrs Mtrans stay at the power injector up to 12 Hours.



Economical:
Easy handling.
Optimize patient flow.



Zero contamination
Safe up to 12hrs based on third party bacteriological and virological study.



12 Hours
Injection System



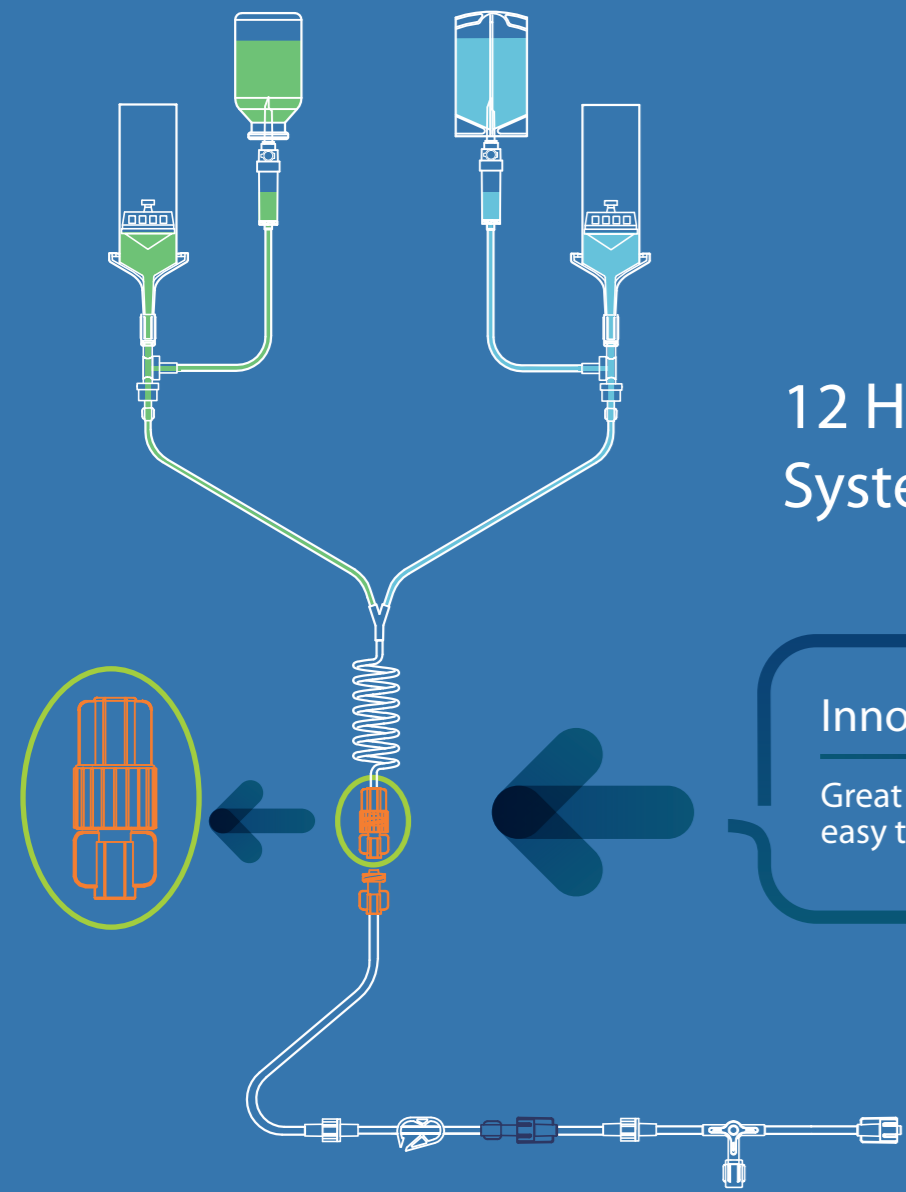
Shenzhen Maiwei Biotech Co., Ltd.

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PN:12 Hours Injection System-210x285-ENG-20200225





12 Hours Injection System (Dual)

Innovative Connector

Great sealing performance, easy to disconnect after usage.

Preparation	In Progress	After use
Make the system air-free. Turn the 3-way stopcock into "open" position between patient and port. Observe the blood backflow.	Possibility for additional medicine injection during examination.	Distal part of Stube can be used as a protective cap until the next patient.

Patented products: PCT/CN2018/104122

①+②+③=Mset		
REF	Description	Operation Time
B04105	LF OptiVantage, Dual, For CT (200ml/200ml Syringes ,150cm 12Hrs Mtrans)	Up to 12 hours or up to 40 examinations

① Mtrans		
REF	Description	Operation Time
D1L110	12hrs Mtrans tube system with inline drip chamber (150cm coiled; dual)	Up to 12 hours or up to 40 examinations

Compatible with Medrad, Medtron, Nemoto, etc... Please consult with **Maiwei**.

Components

12 Hrs Mtrans

Timing Card

Syringes

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Stube, many more Safety Tubes with 2NRV can be used.

① Mtrans			
REF	PN	Description	Picture
D1L105	0402-001-1892	12hrs Mtrans tube system with inline drip chamber (50cm straight ; dual)	Drip Chamber Optional
D1L106	0402-001-1902	12hrs Mtrans tube system with drip chamber (50cm straight ; dual)	
D1L110	0402-001-1932	12hrs Mtrans tube system with inline drip chamber (150cm coiled ; dual)	
D1L111	0402-001-1942	12hrs Mtrans tube system with drip chamber (150cm coiled ; dual)	
D1L107	0402-001-1912	12hrs Mtrans tube system with inline drip chamber (50cm straight ; dual) , PFS	Drip Chamber Optional
D1L108	0402-001-1922	12hrs Mtrans tube system with drip chamber (50cm straight ; dual) , PFS	
D1L112	0402-001-1952	12hrs Mtrans tube system with inline drip chamber (150cm coiled ; dual) , PFS	
D1L113	0402-001-1962	12hrs Mtrans tube system with drip chamber (150cm coiled ; dual) , PFS	

④ Stube			
Basic			
REF	PN	Description	Picture
SOL112	0402-001-1982	Safety tube with disconnection (2 valves)	
SOL120 SOL121 SOL122 SOL128 SOL132	0402-001-1992 0402-001-2002 0402-001-2012 0402-001-2022 0402-001-2032	Safety tube without disconnection (2 valves)	

Standard			
REF	PN	Description	Picture
SOL110	0402-001-1972	Safety tube with disconnection (2 valves & three-way)	
SOL155	0402-001-2062	Safety tube without disconnection (2 valves & filter)	
SOL124	0402-001-2072	Safety tube without disconnection (2 valves & three-way)	

Advanced			
REF	PN	Description	Picture
SOL114	0402-001-2052	Safety tube with disconnection (2 valves & three-way & filter)	
SOL126	0402-001-2082	Safety tube without disconnection (2 valves & three-way & filter)	

Also available with traditional luer-lock connection, please consult with Maiwei.