

•••••
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:



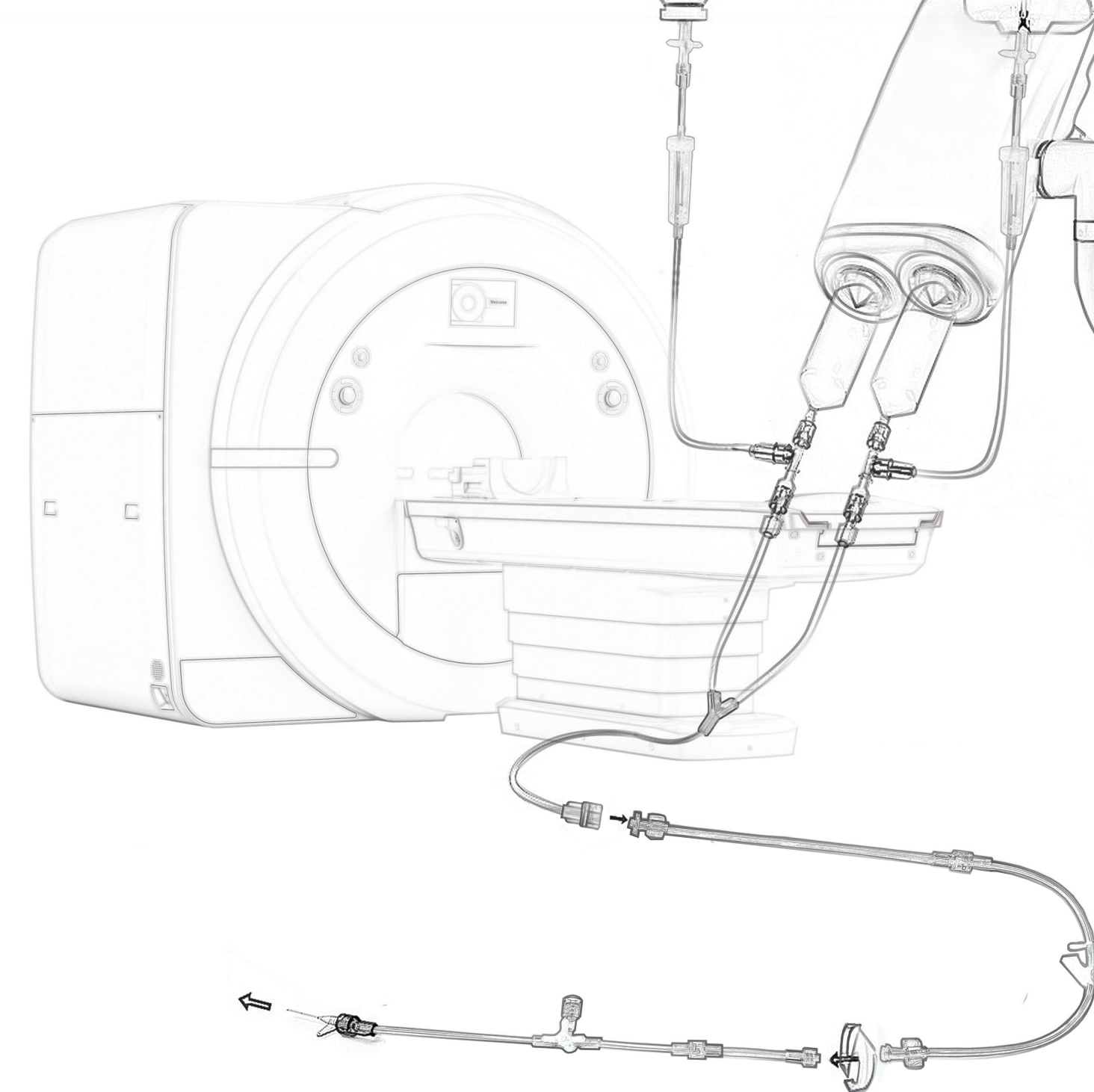
Cost saving
The system allows the syringes and 12hrs Mtrans stay at the power injector up to 12 Hours.



Economical:
Easy handling.
Optimize patient flow.



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



12 Hours
Injection System



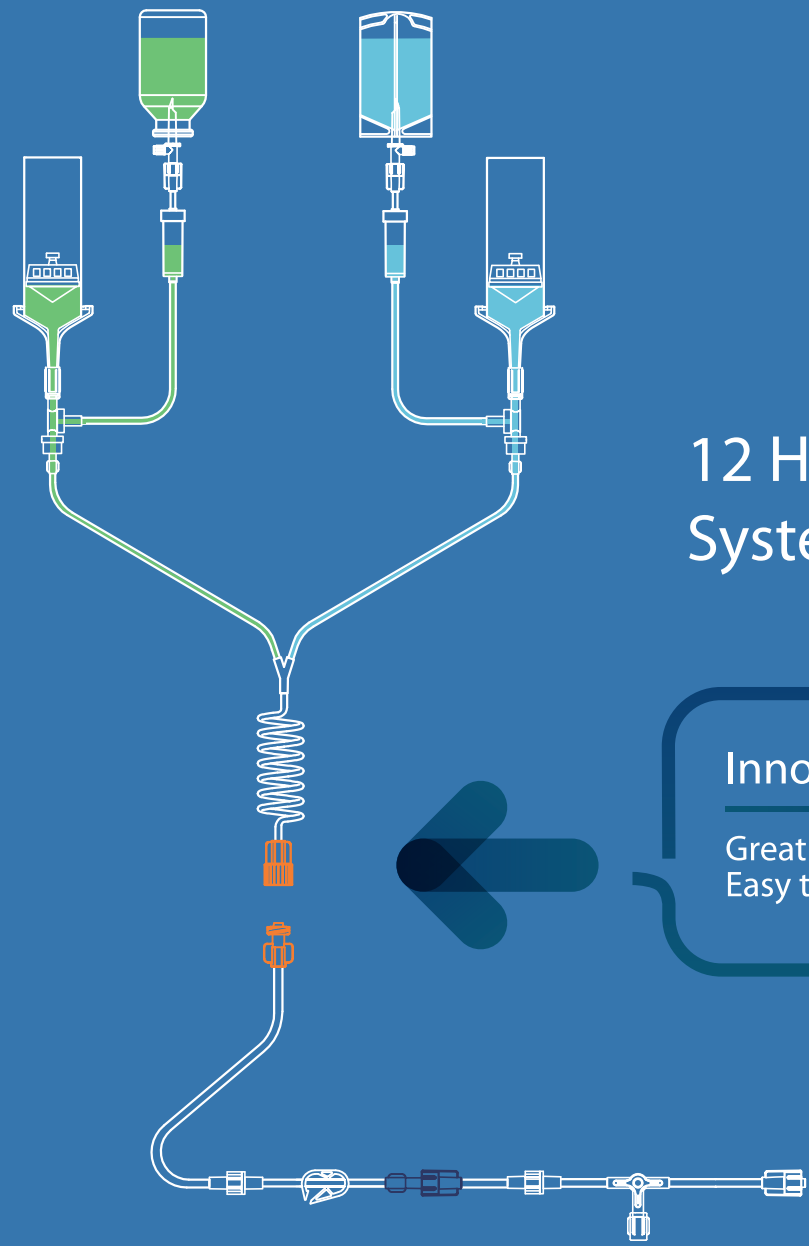
Shenzhen Maiwei Biotech Co., Ltd.

2/F, Building 1, No. 2-10, Jinlong Blvd. South, Pingshan District, Shenzhen, P.R. China
Tel: +86 755 85222663 Fax: +86 755 85222785
E-mail: ecr2020@maiweibio.com http://www.maiweibio.com



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



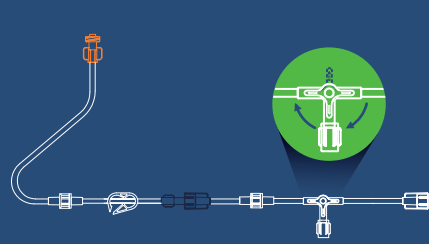


12 Hours Injection System (Dual)

Innovative Connector

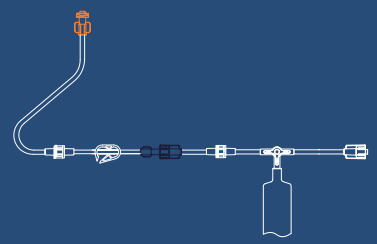
Great sealing performance,
Easy to disconnect after use.

Preparation



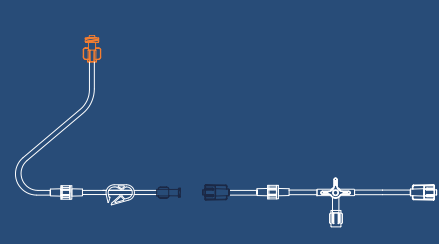
Make the system Air-Free. Turn the 3-Way Stopcock into "open" position between patient and port. Observe the blood backflow.

In Progress



Possible additional medicine injection during examination.

After use



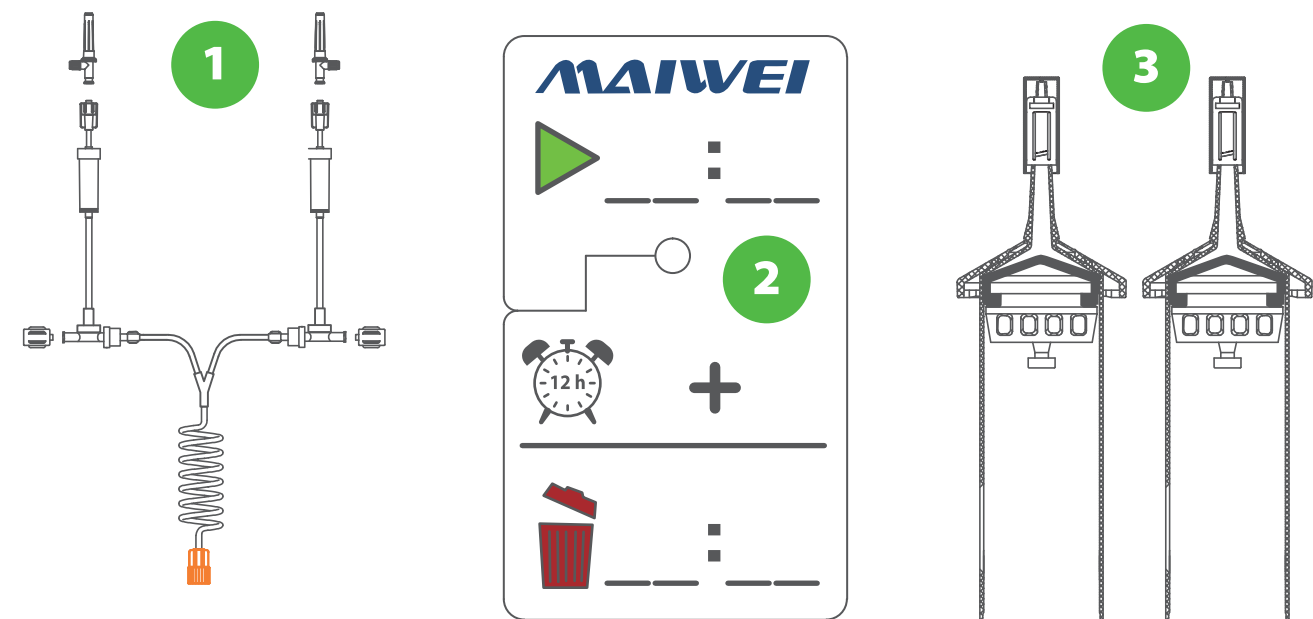
Distal part of Stube can be used as protective cap until the next patient.

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

① Mtrans		
REF	Description	Operation Time
D1L010	350PSI,150cm 12Hrs Mtrans tubing system)	Up to 12 hours

💡 Compatible with Medrad, Medtron, Nemoto, Etc.... Please consult with **Maiwei**.

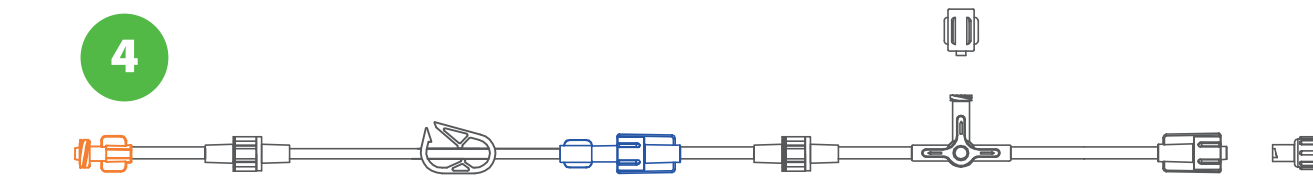
Components



12 Hrs Mtrans

Timing Card

Syringes



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

④ Stube

Stube (Basic)			
REF	PN	Description	Picture
SOL040	0402-001-1472	350psi; With Double Check Valve	
SOL012	0402-001-1502	350psi; With Two Check Valves	
SOL020	0402-001-1442	350psi; With Two Check Valves	

Stube (Standard)			
REF	PN	Description	Picture
SOL042	0402-001-1482	350psi; With Double Check Valve and 3-Way Stopcock	
SOL010	0402-001-1002	350psi; With Two Check Valves and 3-Way Stopcock	
SOL024	0402-001-1452	350psi; With Two Check Valves and 3-Way Stopcock	

Stube (Advanced)			
REF	PN	Description	Picture
SOL044	0402-001-1492	350psi; With Double Check Valve, 3-Way Stopcock and Particle Filter	
SOL014	0402-001-1512	350psi; With Two Check Valves, 3-Way Stopcock and Particle Filter	
SOL026	0402-001-1462	350psi; With Two Check Valves, 3-Way Stopcock and Particle Filter	

💡 Available in straight or coiled tube. Please consult with **Maiwei**.