

Device name: Disposable high pressure syringe

Doc. Name: Instructions for Use

Doc. No.: TD/EF/09/004-06

Doc. version: A/1

Written by: Leibo.Xin Date:2025.12.12

Reviewed by: Wenguo Zhang Date:2025.12.12

Approved by: Dongcheng Li Date:2025.12.12

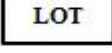
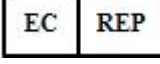
Union Medical Shenzhen Co.,Ltd.

Revision History Record

Revision	Description	Written by	Reviewed by	Approved by	Date
A/0	First release	Leibo.Xin	Wenguo Zhang	Dongcheng Li	2024.12.18
A/1	The sentence of <i>contra-indications</i> has been rephrased.	Leibo.Xin	Wenguo Zhang	Dongcheng Li	2025.12.12

Instructions for Use

● Symbol

Symbol	Description
	Caution
	Non-Pyrogenic
	Do not re-use
	Do not re-sterilize
	Date of manufacture
	Use-by date
	Batch code
	Single sterile barrier system, sterilized using ethylene oxide
	Indicates the device conforms to the requirements of the European regulation (EU) 2017/745.
	Authorized representative in the European Community.
	Manufacturer
	Medical device



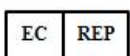
Union Medical Shenzhen Co., Ltd.

Room 603, Building 3, Fantasia MIC Plaza, Nanhai Avenue,

Nanshan District, 518062, Shenzhen, P.R.China

Tel: +86 (755) 2669-6966

Fax: +86 (755) 2681-8966



Shanghai International Holding Corp. GmbH (Europe)

Eiffestrasse 80, D-20537, Hamburg, Germany

Tel: +49-40-2513175

Fax: +49-40-255726

● **Product name:** Disposable High Pressure Syringe

● **Introduction:** Please carefully read the information contained in these instructions for use. These instructions for use are applicable to Disposable High Pressure Syringe, the models of which are indicated as follows.

No.	Models (REF) UDI-DI	Contents	Specification	Pressure Limit	Applicable Injection Systems
1	SMR101 (01) 0 697028690 001 8	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	MEDRAD Vistron, Envision CT
2	SMR102 (01) 0 697028690 002 5	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	MEDRAD Stellant CT
3	SMR103 (01) 0 697028690 003 2	1-125ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	125ml	2.4Mpa (350psi)	MEDRAD Vistron, Envision CT
4	SMR104 (01) 0 697028690 004 9	2-200ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	MEDRAD Stellant CT
5	SMR105 (01) 0 697028690 048 3	1-190ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-short spike	190ml	2.4Mpa (350psi)	Imaxeon Salient
6	SMR106 (01) 0 697028690 061 2	2-190ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	190/190ml	2.4Mpa (350psi)	Imaxeon Salient
7	SMR301 (01) 0 697028690 009 4	2-65ml Syringes 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/65ml	2.4Mpa (350psi)	MEDRAD Spectris MR
8	SMR302 (01) 0 697028690 010 0	1-115ml Syringe 1-65ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/115ml	2.4Mpa (350psi)	MEDRAD Spectris Solaris MR
9	SMR303 (01) 0 697028690 211 1	1-115ml Syringe 1-65ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/115ml	2.4Mpa (350psi)	MEDRAD Spectris Solaris MR
10	SLF101 (01) 0 697028690 011 7	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-Prime Tube	200ml	2.4Mpa (350psi)	LF CT9000, CT9000 ADV
11	SLF102 (01) 0 697028690 012 4	2-200ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	LF OptiVantage Dual Head CT
12	SLF103 (01) 0 697028690 034 6	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-Prime Tube	200ml	2.4Mpa (350psi)	LF OptiVantage Dual Head CT
13	SLF104 (01) 0 697028690 035 3	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-Prime Tube	200ml	2.4Mpa (350psi)	LF OptiVantage Dual Head CT

14	SLF105 (01) 0 697028690 036 0	1-200ml Syringe 1-long spike 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	LF OptiVantage Dual Head CT
15	SLF106 (01) 0 697028690 060 5	1-200ml Syringe	200ml	2.4Mpa (350psi)	LF CT9000, CT9000 ADV
16	SLF107 (01) 0 697028690 054 4	1-125ml syringe 1-150cm Connector Tube 1- long spike 1- Quick Fill Tube	125ml	2.4Mpa (350psi)	LF Mallinckrodt Optivantage
17	SLF301 (01) 0 697028690 015 5	2-60ml Syringes 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	60/60ml	2.4Mpa (350psi)	LF OPTISTAR MR
18	SNE101 (01) 0 697028690 016 2	1-100ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-long spike	100ml	2.4Mpa (350psi)	NEMOTO A-25,A-60
19	SNE102 (01) 0 697028690 017 9	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-Prime Tube	200ml	2.4Mpa (350psi)	NEMOTO A-60
20	SNE103 (01) 0 697028690 018 6	1-200ml Syringe 1-60ml Syringe 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/60ml	2.4Mpa (350psi)	Nemoto Dual Shot CT
21	SNE104 (01) 0 697028690 019 3	1-200ml Syringe 1-100ml Syringe 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/100ml	2.4Mpa (350psi)	Nemoto Dual Shot CT
22	SNE105 (01) 0 697028690 037 7	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube 1-short spike 1-Prime Tube	200ml	2.4Mpa (350psi)	Nemoto Dual Shot CT
23	SNE106 (01) 0 697028690 038 4	1-100ml Syringe 1- short spike	100ml	2.4Mpa (350psi)	Nemoto Dual Shot CT
24	SNE107 (01) 0 697028690 066 7	2-200ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	Nemoto Dual Shot CT
25	SNE301 (01) 0 697028690 021 6	2-60ml Syringes 1-250cm Connector Tube (Y tube with one check-valve) 1-long spike for saline 1-short spike for contrast	60/60ml	2.4Mpa (350psi)	NEMOTO MRI
26	SMT101 (01) 0 697028690 022 3	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	Medtron Accutron CT
27	SMT102 (01) 0 697028690 023 0	2-200ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	Medtron Accutron CT-D

28	SMT103 (01) 0 697028690 059 9	1-200ml Syringe	200ml	2.4Mpa (350psi)	Medtron Accutron CT
29	SMT104 (01) 0 697028690 062 9	2-200ml Syringes 1-180cm Connector Tube 1-150cm Connector Tube	200/200ml	2.4Mpa (350psi)	Medtron CT
30	SMT105 (01) 0 697028690 063 6	2-200ml Syringes 1-150cm Connector Tube 1-180cm Connector Tube 2-Quick fill tubes	200/200ml	2.4Mpa (350psi)	Medtron CT
31	SMT301 (01) 0 697028690 024 7	2-65ml Syringes 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/65ml	2.4Mpa (350psi)	Medtron MRI
32	SMT302 (01) 0 697028690 212 8	1-200ml Syringe 1-65ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/65ml	2.4Mpa (350psi)	Medtron MRI
33	SEZ101 (01) 0 697028690 025 4	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	EZEM EmpowerCT
34	SEZ102 (01) 0 697028690 058 2	2-200ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	EZEM EmpowerCT
35	SEZ301 (01) 0 697028690 056 8	2-100ml Syringes 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	100/100ml	2.4Mpa (350psi)	EZEM EmpowerMR
36	SSC101 (01) 0 697028690 032 2	1-100ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	100ml	2.4Mpa (350psi)	Seacrown Zenith-C10
37	SSC102 (01) 0 697028690 033 9	2-100ml Syringes 1-150cm Connector Tube 2-Quick Fill Tube	100/100ml	2.4Mpa (350psi)	Seacrown Zenith-C11
38	SSC103 (01) 0 697028690 040 7	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200ml	2.4Mpa (350psi)	Seacrown Zenith-C20
39	SSC104 (01) 0 697028690 041 4	2-200ml Syringes 1-150cm Connector Tube 2-Quick Fill Tube	200/200ml	2.4Mpa (350psi)	Seacrown Zenith-C22
40	SSC301 (01) 0 697028690 044 5	2-65ml Syringes 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/65ml	2.4Mpa (350psi)	Seacrown Zenith-C60
41	SSC302 (01) 0 697028690 045 2	1-115ml Syringe 1-65ml Syringe 1-250cm Connector Tube 1-long spike for saline 1-short spike for contrast	65/115ml	2.4Mpa (350psi)	Seacrown Zenith-C66
42	SYW101 (01) 0 697028690 046 9	1-190ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	190ml	2.4Mpa (350psi)	Imaxeon Salient
43	SYW102 (01) 0 697028690 047 6	2-190ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	190/190ml	2.4Mpa (350psi)	Imaxeon Salient

44	SSN101 (01) 0 697028690 026 1	1-200ml Syringe 1-150cm Connector Tube 1-Quick Fill Tube	200/200ml	2.4Mpa (350psi)	Sino Power-D
45	SSN102 (01) 0 697028690 027 8	2-200ml Syringes 1-150cm Connector Tube 1-long spike for saline 1-short spike for contrast	200/200ml	2.4Mpa (350psi)	Sino Power-D
46	SMR201 (01)0 697028690 005 6	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	MEDRAD Mark V Injection System
47	SMR202 (01)0 697028690 006 3	1-200ml Syringe 1-Quick Fill Tube	200ml	8.3Mpa (1200psi)	MEDRAD Mark V Injection System
48	SMR203 (01)0 697028690 007 0	1-60ml Syringe 1-Quick Fill Tube	60ml	8.3Mpa (1200psi)	MEDRAD Mark V Injection System
49	SMR204 (01)0 697028690 008 7	1-130ml Syringe 1-Quick Fill Tube	130ml	8.3Mpa (1200psi)	MEDRAD Mark IV Injection System
50	SMR205 (01)0 697028690 049 0	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	MEDRAD Mark 7
51	SLF201 (01)0 697028690 013 1	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	LF Angiomat 6000 Injection System
52	SLF202 (01)0 697028690 014 8	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	LF Angiomat Illumena Injection System
53	SLF203 (01)0 697028690 039 1	1-200ml Syringe 1-Quick Fill Tube	200ml	6.2Mpa (900psi)	LF Illumena
54	SMT201 (01)0 697028690 064 3	1-200ml Syringe 1-Quick Fill Tube	200ml	8.3Mpa (1200psi)	Medtron Angiography
55	SMT202 (01)0 697028690 0650	1-200ml Syringe	200ml	8.3Mpa (1200psi)	Medtron Angiography
56	SNE201 (01)0 697028690 020 9	1-120ml Syringe 1-Quick Fill Tube	120ml	8.3Mpa (1200psi)	NEMOTO 120S Injection System
57	SNE202 (01)0 697028690 067 4	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	Nemoto, PressPro , Nemoto Rempress
58	SSC201 (01)0 697028690 042 1	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	Seacrown Zenith-H15
59	SSC202 (01)0 697028690 043 8	1-150ml Syringe 1-Quick Fill Tube	150ml	8.3Mpa (1200psi)	Seacrown Zenith-A10, H10, D10

● Important Safety Notice

- a- The device is intended to be used by individuals with adequate training and experience in diagnostic imaging studies.
- b- As with any injector, operator vigilance is required when using the power injector syringes. Visual inspections and good practice during set-up and use, and compliance with the operator's manual remain the primary methods to limit the risk of air being present during fluid delivery.
- c- Make sure that the device is not expired before use. Move the device into the room at least 48 hours before using.
- d- Disposable products, don't re-use.
- e- In case of leakage or crack of the device, stop using it immediately. Treat the patient and product properly and report to the competent authorities.

f- These devices are not intended for multiple-use, drug infusion, chemotherapy, or any other use for which the device is not indicated.

● **Intended use:** The devices are intended to be used in the delivery of contrast media. These devices are indicated for single-use only with CT ,MRI and DSA power injectors.

● **Indications:** Patients who need to inject contrast agent for enhancing examinations of body parts.

● **Contra-indications:** The devices are not intended for those patients with weak blood vessels, severe heart diseases, and allergy to contrast agents.

● **Residual risk and undesirable side-effects:** When the contrast agent touches the inner wall of the device a small amount of substances will be precipitated, which may enter the body with contrast media. The amount of precipitation is far below the requirements of EU regulations due to the short time of using the device.

● **Specification of the clinical benefits:** Using the device to inject contrast agent can improve the quality of medical images, thus increase the diagnostic accuracy.

● **Warning**

Air Embolism Hazard. Serious patient injury or death may result.

- a- Ensure that one operator is designated as being responsible for filling and refilling the syringe. Do not change operators during the procedure. If an operator change must occur, ensure that the new operator verifies that the fluid path is purged of air.
- b- Ensure that patient is not connected while purging air from syringe, or engaging or advancing plunger.
- c- Orient the Injector Head to the Purge (upright) position during filling of syringe and purging of air.
- d- Purge all air out of syringe and any and all disposables after filling.
- e- Tap syringe after filling to facilitate air removal.
- f- Verify that the elliptical dot indicators are rounded to ensure that fluid is present in the syringe.

Bloodborne Contamination Hazard. Serious patient and/or worker injury or death may result.

- a- Use caution when removing air from the syringe. Component damage may result from the use of tools during air removal.
- b- When the procedure has been completed, ensure that the patient has been disconnected from the system.
- c- Press the backward button on the injector head or turn the Manual Knob counter-clockwise to retract the syringe plunger 2-3ml.

Biological Contamination Hazard. Serious patient and/or worker injury or death may result.

- a- Properly discard disposables after use or if contamination may have occurred during setup or use.

Environmental Contamination Hazard. Patient and/or worker injury may result.

- a- Visually inspect contents and package before each use and do not use if package is opened or damaged.
- b- Follow sterile technique principles, specifically, maintain sterility of the syringe tip and plunger,

syringe barrel internal surface, Quick Fill Tube, and spike.

- c- Do not scrape off dried, potentially contaminated contrast into recesses during syringe installation.

Bacterial Contamination Hazard. Patient and/or worker injury may result.

- a- Use filled syringes immediately.
- b- Do not store filled syringe for later use.
- c- Discard previously filled unused syringes.

● **Syringe Installation**

Install a Syringe (or Syringes) according to the power injector operation manual which the syringe fits.

● **Syringe Filling**

- a- Tilt the injector head (or the syringe interface module) up.
- b- Advance the plunger to full forward position.
- c- Remove the protective cover from the syringe luer tip and attach a sterile filling device (Quick Fill Tube, spike) onto the tip of the syringe.
- d- Transfer the contrast media into the syringe by one of following methods:
 - Quick Fill Tube: raise the contrast bottle until the Quick Fill Tube is fully inserted. The end of the Quick Fill Tube should be near the bottom of the contrast bottle.
 - Spike: prepare the bottle or bag of contrast and/or flushing solution. Push the bottle or bag onto the Filling Device until the seal is punctured, long spike for saline, short spike for contrast.

NOTE: Use Quick Fill Tube or equivalent device to reduce the volume and size of air bubbles drawn into the syringe during filling. It is more difficult to remove the air bubbles if you use smaller diameter tubes, such as catheter-over-needle, or a tube longer than 10 inch (25cm)

- e- Aspirate contrast media into the syringe.
- f- If the syringe has dot indicators use them to help you detect the presence of contrast media in the syringe. Verify that the Syringe disposable dot indicators are round in the filled portion of the syringe. The rounded shape of the dot indicators varies according to the type of contrast media, but an oblong shape indicates the presence of air. Rounded dot indicators do not indicate the total absence of air bubbles in the syringe tip.



- g- If required, use your free hand to gently tap the syringe to facilitate migration of air bubbles remaining within the syringe and on the syringe plunger to the syringe tip.

● **Purging Air and Attaching the Connector Tube**

After you fill the syringe, you must purge all air from the syringe and then attach the connector tubing. To do so:

- a- Remove the filling device and purge air from the syringe. Do not hit the syringe to remove air

bubbles. Reverse the plunger 3 to 5 ml, then, if applicable, rock the injector head on the pivot to dislodge the bubbles. Purge the remaining air.

- b- If you are using a connector tube with an integrated checkvalve, attach the straight portion to the contrast (Syringe A) and the extension to the saline (Syringe B). While if you are using a connector tube with dual checkvalves, attach either portion to the contrast (Syringe A), and the other portion to the saline (Syringe B). Do not reverse the piston plunger on Syringe A after you have attached the tube.
- c- Verify that the tubing is not kinked or obstructed.
- d- Use the manual knob or forward button on injector head to advance the syringe plunger to provide a slow flow of contrast media through the connector tubing. An absence of flow is an obvious indication of air in the fluid path.
- e- Prime the connector tubing and make certain that the air is purged.
- f- Verify that all air has been purged from the syringe and fluid path.
- g- Attach the connector tube to the vascular entry device.
- h- Tilt the injector head (or syringe interface module) down.

● Syringe Reinstallation

If you remove a syringe from the injector and then wish to reinstall it, perform the following steps:

- a- Insert the end of the syringe in the horizontal cutouts in the injector head.
- b- Advance the piston until it is past the plunger feet and the piston and plunger interlock.
- c- Install the syringe according to the power injector operation manual which the syringe fits, until the syringe locks and alignment marks are positioned.
- d- Proceed as normal by aspirating and dislodging any bubbles.

● Syringe Removing

- a- To detach the syringe when the procedure has been completed, remove it from the injector head. Discard all used components.
- b- Do not use unless the plunger feet are properly engaged with the piston.
- c- Do not reuse disposables.

● Disposal after use

- a- Dispose used products after use, and according to the hospital disposal regulations of disposables.

● Instructions of Product maintenance, storage, and transport

- a- This product should be stored in a room without direct sunlight, relative humidity not exceeding 80%RH, temperature between -20 °C ~ 40 °C, no corrosive gas, well ventilated and clean.
- b- The product should be transported and handled with care, and is not allowed to be thrown or dropped. The stacking height should not exceed 6 layers.



Date of issue: 12 Dec 2025