

SATsyringe DISPOSABLE HIGH PRESSURE SYRINGE & ACCESSORIES

Technical Sheet - Reference Injector Models (MEDRAD)
Ver. SMH/S2602



FDA 510K Cleared



SKU No.
Reference Injector
Model

72233B1
MEDRAD Salient (CT)



72233B2
MEDRAD Stellant (CT)



72233B3
MEDRAD MRXperion (MRI)



72233B4
MEDRAD Spectris Solaris (MRI)



Parameter	Specification			
Product Name	Disposable high pressure syringe and accessories			
Device Group	Syringe for contrast media injector, single-use			
Composition	2 × 200 mL syringes 2 × spikes	2 × 200 mL syringes 2 × spikes	1 × 65 mL syringe 1 × 115 mL syringe 2 × spikes	1 × 65 mL syringe 1 × 115 mL syringe 2 × spikes
Maximum Pressure	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa
Connection Method	Connected to contrast agent syringe by plunger			
Classification	Class IIa EU 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)			
Standard Compliance	YY/T 0614-2017			
EMDN code	A02010401			
Material	Syringe: consists of barrel (PP / PET), plunger (PP / PC), piston (IR) and other parts			
Sterility Method	Ethylene oxide (EO)			
Shelf Life	3 Years			
Primary Packaging	Hard plastic blister tray 1 set / tray			
Secondary Packaging	30 trays / carton	30 trays / carton	50 trays / carton	50 trays / carton



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Note:

The composition listed above is the standard configuration; **customization** is available upon request to meet specific clinical needs.

The information in this technical sheet is subject to change without prior notice as part of our continuous product improvement policy.

SATsyringe DISPOSABLE HIGH PRESSURE SYRINGE & ACCESSORIES

Technical Sheet - Reference Injector Models (GUERBET LF)
Ver. SMH/S2602



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SKU No.	72233G1	72233G2	72233G3
Reference Injector Model	Illumena Néo (Angio/CT)	OptiVantage (CT)	OptiStar Elite (MRI)



Parameter	Specification		
Product Name	Disposable high pressure syringe and accessories		
Device Group	Syringe for contrast media injector, single-use		
Composition	1 × 150 mL syringe 1 × J quick fill tubing	2 × 200 mL syringes 2 × spikes	2 × 60 mL syringes 2 × spikes
Maximum Pressure	1,200 PSI / 8,274 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa
Connection Method	Connected to contrast agent syringe by plunger		
Classification	Class IIa EU 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)		
Standard Compliance	YY/T 0614-2017		
EMDN code	A02010401		
Material	Syringe: consists of barrel (PP / PET), plunger (PP / PC), piston (IR) and other parts		
Sterility Method	Ethylene oxide (EO)		
Shelf Life	3 Years		
Primary Packaging	Hard plastic blister tray 1 set / tray		
Secondary Packaging	60 trays / carton	30 trays / carton	50 trays / carton



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SATsyringe DISPOSABLE HIGH PRESSURE SYRINGE & ACCESSORIES

Technical Sheet - Reference Injector Models (MEDTRON)
Ver. SMH/S2602



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SKU No.
Reference Injector
Model

72233M1
Accutron MR (MRI)



72233M2
Accutron CT-D (CT)



72233M3
Accutron CT (CT)



Parameter	Specification		
Product Name	Disposable high pressure syringe and accessories		
Device Group	Syringe for contrast media injector, single-use		
Composition	2 × 60 mL syringes 2 × spikes	2 × 200 mL syringes 2 × spikes	1 × 200 mL syringe 1 × spike
Maximum Pressure	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa
Connection Method	Connected to contrast agent syringe by plunger		
Classification	Class IIa EU 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)		
Standard Compliance	YY/T 0614-2017		
EMDN code	A02010401		
Material	Syringe: consists of barrel (PP / PET), plunger (PP / PC), piston (IR) and other parts		
Sterility Method	Ethylene oxide (EO)		
Shelf Life	3 Years		
Primary Packaging	Hard plastic blister tray 1 set / tray		
Secondary Packaging	50 trays / carton	30 trays / carton	50 trays / carton



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SATsyringe DISPOSABLE HIGH PRESSURE SYRINGE & ACCESSORIES

Technical Sheet - Reference Injector Models (NEMOTO)
Ver. SMH/S2602



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SKU No.	72233N1	72233N2	72233N3	72233N4	72233N5	72233N6
Reference Injector Model	Nemoto A60 (CT)	Nemoto A60 (CT)	Nemoto A60 (CT)	Nemoto Dual Shot Alpha7 (CT)	Nemoto 120S (Angio/CT)	Nemoto Sonic Shot 7 (MRI)
						

Parameter	Specification					
Product Name	Disposable high pressure syringe and accessories					
Device Group	Syringe for contrast media injector, single-use					
Composition	1 × 100 mL syringe 1 × spike	1 × 200 mL syringe 1 × spike	1 × 100 mL syringe 1 × 200 mL syringe 2 × spikes	2 × 200 mL syringes 2 × spikes	1 × 130 mL syringe 1 × J quick fill tubing	2 × 60 mL syringes 2 × spikes
Maximum Pressure	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	350 PSI / 2,413 kPa	1,200 PSI / 8,274 kPa	350 PSI / 2,413 kPa
Connection Method	Connected to contrast agent syringe by plunger					
Classification	Class IIa EU 2017/745 on Medical Devices, Annex IX Chapters I and IIII (Class IIa and Class IIb Devices)					
Standard Compliance	YY/T 0614-2017					
EMDN code	A02010401					
Material	Syringe: consists of barrel (PP / PET), plunger (PP / PC), piston (IR) and other parts					
Sterility Method	Ethylene oxide (EO)					
Shelf Life	3 Years					
Primary Packaging	Hard plastic blister tray 1 set / tray					
Secondary Packaging	60 trays / carton	50 trays / carton	30 trays / carton	30 trays / carton	60 trays / carton	50 trays / carton



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SATSyringe MULTI-PATIENT HIGH-PRESSURE SYRINGE

Version: SMH/S2609-24H



SKU No.	72233B1-24H	72233B2-24H	72233G2-24H	72233M2-24H	72233M3-24H
Reference Injector Model	MEDRAD Salient (CT)	MEDRAD Stellant (CT)	OptiVantage (CT)	Accutron CT-D (CT)	Accutron CT (CT)

Parameter	Specification				
Product Name	High-Pressure Syringe				
Device Group (EMDN)	A020299 - REUSABLE SYRINGES - OTHER				
Set Configuration	2 × 200 mL syringes	2 × 200 mL syringes	2 × 200 mL syringes	2 × 200 mL syringes	1 × 200 mL syringe
Maximum Pressure	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa
Intended Use	The high pressure syringe is intended for use with compatible high-pressure injection equipment for the injection of contrast medium, saline, or other applicable liquid medication during diagnostic imaging and angiographic procedures. The Device may be used in X-ray-based imaging procedures, including computed tomography (CT) and digital subtraction angiography (DSA), as well as magnetic resonance (MR) imaging, when used with compatible equipment and accessories.				
Classification	Class IIa, rule 2				
Conformity Assessment	Regulation (EU) 2017/745 (MDR), Annex IX, Chapters I and III				
Maximum Usage	Up to 24 hours or 90 injections, whichever occurs first				
Material	Barrel: PP/PET; Plunger: PP/PC; Piston: Isoprene rubber (IR); other components as applicable				
Sterilization Method	Ethylene oxide (EO)				
Shelf Life	3 years from the date of manufacture				
Primary Packaging	Hard plastic blister tray; 1 set / tray				
Secondary Packaging	30 trays / carton	30 trays / carton	30 trays / carton	30 trays / carton	50 trays / carton



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SATSyringe MULTI-PATIENT HIGH-PRESSURE SYRINGE

Version: SMH/S2609-24H



SKU No.	72233N2-24H	72233N4-24H	72233E1-24H	72233E2-24H	72233E3-24H
Reference Injector Model	Nemoto A60 (CT)	Nemoto Dual Shot Alpha7 (CT)	EmpowerCT (CT)	EmpowerCTA (CT)	EmpowerMR (MRI)
					

Parameter	Specification				
Product Name	High-Pressure Syringe				
Device Group (EMDN)	A020299 - REUSABLE SYRINGES - OTHER				
Set Configuration	1 × 200 mL syringe	2 × 200 mL syringes	1 × 200 mL syringe	2 × 200 mL syringes	2 × 100 mL syringes
Maximum Pressure	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa	350 PSI / 2,400 kPa
Intended Use	The high pressure syringe is intended for use with compatible high-pressure injection equipment for the injection of contrast medium, saline, or other applicable liquid medication during diagnostic imaging and angiographic procedures. The Device may be used in X-ray-based imaging procedures, including computed tomography (CT) and digital subtraction angiography (DSA), as well as magnetic resonance (MR) imaging, when used with compatible equipment and accessories.				
Classification	Class IIa, rule 2				
Conformity Assessment	Regulation (EU) 2017/745 (MDR), Annex IX, Chapters I and III				
Maximum Usage	Up to 24 hours or 90 injections, whichever occurs first				
Material	Barrel: PP/PET; Plunger: PP/PC; Piston: Isoprene rubber (IR); other components as applicable				
Sterilization Method	Ethylene oxide (EO)				
Shelf Life	3 years from the date of manufacture				
Primary Packaging	Hard plastic blister tray; 1 set / tray				
Secondary Packaging	50 trays / carton	30 trays / carton	50 trays / carton	30 trays / carton	50 trays / carton



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