Coronary Intravascular Lithotripsy (IVL) Catheter

Instructions For Use

[Product Name]

Generic name: Coronary Intravascular Lithotripsy (IVL) Catheter

Trade name: Sonico-CX

[Intended Purpose]

Coronary Intravascular Lithotripsy (IVL) Catheter and Intravascular Lithotripsy Generator are intended to treat calcified stenosis, including calcified stenoses that are anticipated to exhibit resistance to full balloon dilatation or subsequent uniform coronary stent expansion.

[Indication]

Coronary Intravascular Lithotripsy (IVL) Catheter and Intravascular Lithotripsy Generator are indicated for lithotripsy-enabled, low-pressure balloon dilatation of calcified, stenotic de novo coronary arteries prior to stenting such as severe coronary artery calcification (CAC).

[Intended patient populations]

The device is intended to be used for adult patients (≥18 years) with calcified primary stenotic coronary artery lesions.

[Intended clinical benefits]

Coronary Intravascular Lithotripsy (IVL) Catheter and Intravascular Lithotripsy Generator provide effective and safe treatment for severe coronary artery calcification, demonstrated by a high rate of clinical success and a low rate of Major Adverse Cardiovascular Events (MACE), which is non-inferior to the current state of the art.

[Model and Specifications] See Table 1.

Table 1 List of Model and Specifications

Model	Specification	Diameter of Balloon (mm)	Length of Balloon (mm)
SWCA-2	25012	2.50	12
	27512	2.75	12
	30012	3.00	12
	32512	3.25	12
	35012	3.50	12
	37512	3.75	12
	40012	4.00	12

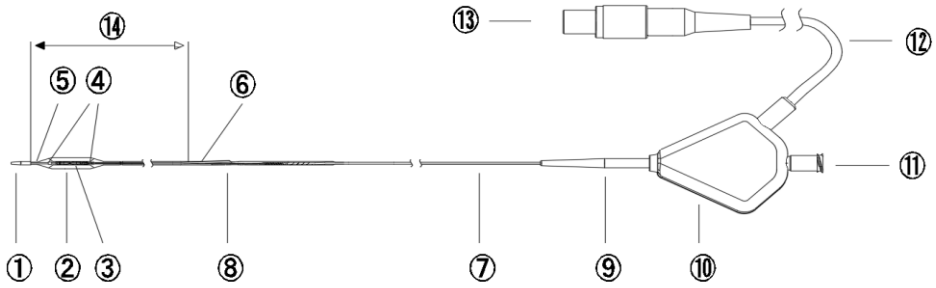
[Operating Principle]

The Coronary Intravascular Lithotripsy (IVL) Catheter is a device that combines acoustic lithotripsy with percutaneous transluminal angioplasty. The calcified target lesion can be reached through the coronary system. After the catheter is connected to the equipment and powered on, the transmitter inside the balloon is activated, and the electrode pairs of the transmitter form a discharge channel to produce arc discharge. The arc discharge produces rapidly resulting in expanding and collapsing bubbles, and the mechanical shock wave formed in the balloon selectively fractures the superficial and deep calcified plaques, causing fatigue and micro-cracks of the calcified plaques in situ, restoring the elasticity of the calcified vessels and improving the compliance of vessels.

[Structure and Composition]

The product consists of a distal tip, balloon, transmitter, radiopaque marker bands, catheter body, guidewire port, strain relief, luer casing assembly, balloon inflation port, equipment connecting cable, equipment connecting plug, and the area from the distal end of the catheter to the guidewire port has a hydrophilic coating.

The product uses a rapid exchange (Rx) design with the inner tube as a guidewire lumen. The guidewire lumen can pass through a 0.014 inch diameter guidewire, and the guidewire port is located in the distal outer tube area. The balloon is positioned at the distal end of the catheter, and the two ends of the effective working length of the balloon are equipped with an opaque X-ray metal (marker bands) that are visible under the angiography for positioning under the balloon image. The pulsed sound pressure wave transmitter is set between the two radiopaque rings. The proximal outer tube is single lumen hypo tube, that is connected to the distal outer tube as an inflation lumen for inflating the balloon, and the luer casing assembly at the proximal end of the catheter has the balloon inflation port, the equipment connecting cable and the equipment connecting plug. The balloon inflation port is equipped with a luer connector and is connected with the inflation lumen for the inflation and deflation of the balloon. The area from the distal end of the catheter to the guidewire port is coated with hydrophilic coating material of polyvinylpyrrolidone (PVP).



1 Distal tip 2 Balloon 3 Transmitter 4 Radiopaque marker bands 5 to 7 Catheter body (5 Inner tube, 6 Distal outer tube, 7 Proximal outer tube) 8 Guidewire port (Rx) 9 Strain relief 10 Luer casing assembly 11 Balloon inflation port 12 Equipment connecting cable 13 Equipment connecting plug 14 Hydrophilic coating area

Figure. 1 Schematic Diagram of Coronary Intravascular Lithotripsy (IVL) Catheter

Note: The applied part of the catheter is from distal tip to proximal outer tube.

[Product Performance]

The diameter and length of balloon expansion is shown in Table 1 above;

Balloon rated burst pressure (RBP) ≥ 12 atm;

The nominal balloon pressure is 6 atm;

The catheter working length is 140 cm ± 5%;

The average acoustic pressure is $1.8^{+3.2}_{-0.8}$ MPa.

Note: This data represents the average acoustic pressure of the balloon's effective working length, which was measured at a position 2mm away from the balloon's surface.

The treatment procedure is shown in Table 2.

Table 2 Treatment Procedures for Coronary Intravascular Lithotripsy (IVL) Catheter

Treatment frequency	1 pulse per second
Maximum number of consecutive pulses (1 cycle)	10 pulses
Minimum pause time (after completion of each cycle)	10 seconds
Maximum number of pulses per piece of catheter	120 (12 cycles)

Notes:

1. The above pulse procedures must be followed during treatment. Whatever size Coronary Intravascular Lithotripsy (IVL) Catheter is connected will initiate the above treatment procedures.

2. After completing each cycle, pause for at least 10 seconds before initiating the next round of treatment. When the catheter has reached the maximum pulse number, the system will automatically stop the treatment. For more information, please refer to our "IFU of Intravascular Lithotripsy Generator".

[Devices intended for combined use with the IVL Catheter]

1. Intravascular Lithotripsy Generator (Model: SPM-2400, SPM-3500) manufactured by Spectrumedics Medical Technology (Shanghai) Co., Ltd.;

2. 6F guiding catheter;

3. 0.014"(0.36 mm) guidewire;

4. 20 mL syringe;

5. Filling device with pressure gauge

6. Sterile protective sleeve (185 cm in length) is used for intraoperative catheter connecting cable.

[How to Use]

Catheter Selection

Refer to the vessel diameter and choose a 1:1 Catheter size. If a 1:1 size is not available, use an adjacent larger diameter balloon (for example, a 4.0 mm Catheter in a vessel with a reference diameter of 4.5 mm).

Balloon Preparation

1. Carefully inspect the catheter and sterilized packaging for damage before use;
2. Open the inner package and remove the catheter during aseptic operation;
3. Fill in 5 mL of contrast agent mixed with normal saline (1:1) into a 20 mL syringe; **Note: Do not use air or any gas to inflate the balloon!**
4. Connect the syringe and the catheter inflation port. Hold the syringe with the nozzle facing down, pull the plunger for about 5 seconds, release the plunger of the syringe, and repeat three times;
5. Fill in 10 mL of contrast agent mixed with normal saline (1:1) into the inflation device. The syringe on the catheter was removed and connected to the inflation device to ensure that the air had been drained;
6. Hold the balloon catheter close to the balloon end with one hand and remove the balloon protective pin;
7. The lumen of the guidewire lumen is cleaned by docking the distal end of the balloon dilation catheter with a syringe filled with sterile heparinized normal saline;
8. Hold the catheter close to the balloon end with one hand, and gently grasp the proximal part of the balloon protective cannula with the other hand and slide it to the distal end until it falls off;
9. Moisten the balloon and the front portion of the catheter with normal saline for more than 15 seconds to activate the hydrophilic coating. Moisten the catheter with a solvent other than normal saline may damage the integrity of the coating;
10. Put the catheter connecting cable of the Intravascular Lithotripsy Generator into a sterile protective sleeve;
11. Insert the equipment connection plug of the catheter into the catheter connecting cable of the Intravascular Lithotripsy Generator to connect the catheter with the Intravascular Lithotripsy Generator.

Insertion Technique

1. Prepare the insertion site using standard sterile techniques;
2. Establish vascular access and place the guiding catheter;
3. A 0.014 inch (0.36 mm) guidewire is inserted across the target lesion under the angiography equipment according to the standard PTCA technique;
4. Insert the proximal end of the guidewire into the distal tip of the catheter;
5. Carefully insert the catheter into the guiding catheter, then push it carefully under the angiography equipment so that it travels through the vessel along the guidewire to the target lesion;

   Notes:

   a. **If resistance is encountered, do not advance the guidewire or balloon catheter until the cause of resistance has been determined and remedial action has been taken.**

   b. **Care should be taken when passing sheathes or other instruments with sharp edges, and through tortuous or calcified vessels, so as not to cause the coating to fall off and remain in the vasculature.**

6. Two radiopaque marker bands on the balloon axis are used as reference points for precise placement across the target lesion, and the effective length of balloon is positioned in the target lesion.

Initiating Acoustic Therapy

1. Inflate the catheter to 4 atm;
2. Start the Intravascular Lithotripsy Generator and release the sound wave pulse according to the procedure set in Table 2;
3. It is recommended that 10 pulses be given to the target lesion site first. After 10 consecutive discharges, the Lithotripsy Generator will be forced to pause for 10 seconds, and the yellow and green light will flash. Pressurize the balloon to the nominal pressure of 6-10 atm (**Note: Do Not exceed with the rated burst pressure**), and observe the treatment effect under X-ray fluoroscopy (if the treatment is satisfactory, the treatment can be terminated);
4. Release the balloon pressure to restore blood flow for 30 seconds;
5. If the doctor is not satisfied with the treatment effect, additional pulse therapy could be performed. According to the shock wave balloon dilatation under X-ray fluoroscopy, until the doctor is satisfied with the treatment effect;
    1) If the number of additional pulses is less than 10 times to achieve patient satisfaction, after stopping the pulse, inflate the balloon to the nominal pressure of 6-10 atm (Note: Do Not exceed with the rated burst pressure), and then deflate the balloon to end the treatment;
    2) If the number of additional pulses reaches 10 times, steps 3, 4 and 5 can be repeated;
    3) After every 10 pulses, the balloon should be deflated for at least 30 seconds to restore the blood flow. The number of pulses at the same target lesion should not exceed 60 times;
6. If the diseased vessel exceeds the length of balloon, the treatment can be repeated after moving the balloon, and the recommended treatment area should be at least 2 mm partial overlap;

    Warning: No more than 120 pulses in an overlap treatment segment.
7. Deflate the balloon after completing the treatment, making sure the balloon has fully contracted and slowly exits the catheter through the guiding catheter;
8. Postoperative angiography is performed to confirm the effect of vasodilatation and the whole system is withdrawn.
9. Do not touch the hand shank during the discharge treatment!

[Precautions]

1. This product is only suitable for use with specialized Intravascular Lithotripsy Generator (when the patient is in use, all components of the system should not be maintained);
2. This product should only be used by professional doctors. Failure to comply with the IFU may result in damage to the device, which may result in serious adverse events.
3. Products that have passed the expiry date should not be used;
4. This product is a disposable sterile product and shall not be reused or sterilized repeatedly. Reuse can lead to severe infections and cross-contamination.
5. Do not use if the packaging is damaged;
6. The system must be used with X-ray imaging equipment with high quality images;

7. If difficulties are encountered during the balloon inflation procedure, the procedure cannot be continued, the catheter should be removed and do not attempt to re-use. It should be replaced with a new catheter;
8. Do not use air or any other gas medium for inflation treatment, otherwise it will lead to uneven expansion and complications;
9. Do not use a diameter of more than 0.014" (0.36 mm) guidewire;
10. Environmental requirements: After use, the products and packaging should be treated in accordance with the relevant requirements of local medical waste disposal.
11. This product is disposable and does not require maintenance.
12. Warning: No modification of this equipment is allowed.
13. NOTICE：If any serious incident occurred in relation to the device, please report to us and the competent authority of the Member State in which you are established.

[Contraindications]

1. The 0.014-inch guidewire cannot pass through the lesion;
2. It is contraindicated in patients whose lesion is diagnosed to be unsuitable for vasodilatation;
3. Pregnant or lactating women are contraindicated;
4. Thrombotic lesions;
5. A single coronary artery for blood supply;
6. Vascular dissection;
7. Graft disease.

[Potential Adverse Reactions]

Potential adverse reactions are consistent with standard catheter-based cardiac interventions and include but are not limited to:

- Acute vascular occlusion
- Overreaction to contrast agent, anticoagulant, and/or antithrombotic therapy
- Aneurysm
- Arrhythmia
- Arteriovenous fistula
- Bleeding complications
- Cardiac tamponade or pericardial effusion
- Cardiopulmonary arrest
- Cerebrovascular accident (CVA)
- Coronary artery/vessel occlusion, perforation, rupture, or dissection
- Coronary artery spasm

- Death
- Emboli (air, tissue, thrombus, or atheromatous emboli)
- Emergency or non-emergency coronary artery bypass grafting
- Emergency or non-emergency percutaneous coronary intervention
- Complications at the puncture site
- Breakage of the guidewire or fail/failure of any component of the device may result in device embolization, dissection, serious injury, or surgical intervention
- Hematoma at the site of vessel puncture
- Bleeding
- Hypertension/hypotension
- Infection/sepsis/fever
- Myocardial infarction
- Myocardial ischemia or unstable angina
- Pain
- Peripheral ischemia
- Pseudoaneurysm
- Renal failure/insufficiency
- Treated coronary artery restenosis leads to revascularization
- Shock/pulmonary edema
- Slow blood flow, no reflow, or sudden coronary occlusion
- Stroke
- Blood clots
- Acute occlusion of a blood vessel
- Vascular Injury that requires surgical repair
- Vascular dissection, perforation, rupture, or spasm

Side-effect identified in the identification from literature search include:

- Major adverse cardiovascular events (MACE): Mainly including cardiac death, target vessel revascularization, and MI.
- Angiographic complications, such as dissections, slow/no flow, and abrupt vessel closure.

In addition, patients may be exposed to other risks associated with coronary intervention procedures, including conscious sedation and local anesthesia, the use of X-ray contrast agents during angiography, medications used to manage subjects during the surgery, and the risk of radiation exposure from fluoroscopy.

Identify risks associated with the device and its use:

- Allergic/immune reactions to the catheter material or coating
- Device failure, failure, or loss of balloon pressure leading to device embolism, dissection, serious injury, or surgical intervention
- Premature atrial or ventricular contractions
- Atrial or ventricular capture

[Mode of Supply]

Coronary Intravascular Lithotripsy (IVL) Catheters are provided after sterilization and can only be used once. Coronary Intravascular Lithotripsy (IVL) Catheters are sterilized with ethylene oxide. Remain sterile as long as the packaging is not opened or damaged. Use before the expiration date indicated on the label.

Note: Do not use if the inner packaging is opened or damaged.

[Transportation Conditions]

The products should be protected from heavy pressure, direct sunlight and rainwater during transportation, or as stipulated in the order contract.

[Storage Conditions]

Products should be stored in a dry, clean, well-ventilated, environment with no corrosive gas at +10℃ ~ +30 ℃.

[Use Environment]

Ambient temperature range: +10℃ ~ +40℃;

Relative humidity range: 30% ~ 75%;

Atmospheric pressure range: 62 kPa ~ 106 kPa.

[Production Date]

See product packaging.

[Shelf Life]

See the product packaging, shelf life of the product is two years.

Note: During clinical use, If the number of pulses exceeds 120 and the surgical procedure has not yet ended, the catheter must be immediately replaced with a new one. When the surgical procedure has ended, even if the number of pulses has not reached 120, it shall be immediately discarded and disposed of.

[Label Symbol Description]

1)		Do not reuse
2)		Follow operating instructions
3)		Keep dry
4)		Production date
5)		Keep away from sunlight
6)		Expiry date
7)		Product reference number
8)		Lot number
9)		Sterilized with ethylene oxide Indicates a single sterile barrier system
10)		Do not use if the packaging is damaged
11)		Caution! Consult accompanying documents
12)		Storage temperature limit +10℃ to +30℃
13)		Manufacturer
14)		Authorized representative information
15)		Medical Devices Direc-tive
16)		CE certification
17)		Defibrillation-proof type CF applied part

[Version of Instructions for Use]

Rev: 06 Date: Nov. 4, 2025

[Electromagnetic Compatibility]

The product complies with IEC 60601-1:2020.

The product has no essential performance.

 Warning:

- Coronary Intravascular Lithotripsy (IVL) Catheter should not be used in close proximity or stacked with other equipment. If they must be used in close proximity or stacked, they should be observed to verify their normal operation in the configuration used.
- Intravascular Lithotripsy Generator (Model: SPM-2400、SPM-3500) equipped by the manufacturer of Coronary Intravascular Lithotripsy (IVL) Catheter should be used. The use of off-label equipment may result in an increase in emission or a decrease in immunity of the Coronary Intravascular Lithotripsy (IVL) Catheter.

- Portable and mobile RF communication equipment may affect the performance of Coronary Intravascular Lithotripsy (IVL) Catheter.

Cable Information

Serial number	Name	Cable length (m)	Shielded or not	Note
1	Equipment connecting wire	0.49	No	/

Guidance and manufacturer's declaration - Electromagnetic emission		
Coronary Intravascular Lithotripsy (IVL) Catheter can be used in the following electromagnetic environments. The customer or user of a Coronary Intravascular Lithotripsy (IVL) Catheter should ensure that it is used in the following environments.		
Emission testing	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	Coronary Intravascular Lithotripsy (IVL) Catheter uses RF energy only for its internal function. As a result, its RF emissions are low and there is little chance of interference with nearby electronic equipment.
RF Emissions CISPR 11	Class A	Coronary Intravascular Lithotripsy (IVL) Catheter is suitable for use in facilities that are not directly connected to the public low-voltage power supply grid of non-homes and domestic residences.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration - Electromagnetic immunity			
Coronary Intravascular Lithotripsy (IVL) Catheter is intended to be used in the electromagnetic environment specified below, and the purchaser or user of Coronary Intravascular Lithotripsy (IVL) Catheter should guarantee that it will be used in this electromagnetic environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV by contact ±15kV through the air	±8kV by contact ±15kV through the air	The ground should be wood, concrete, or tile, and if the ground is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / Burst IEC 61000-4-4	±2kV of power supply lines ±1kV for input/output lines	SPM-2400: ±2kV of power supply lines Not applicable SPM-3500: ±2kV of power supply lines	Mains supply shall have the quality used in typical commercial or hospital environment.

		±1kV for input/output lines	
Surge IEC 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	SPM-2400: ±1kV line(s) to line(s) ±2kV line(s) to earth SPM-3500: ±1kV line(s) to line(s) Not applicable	Mains supply shall have the quality used in typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut 100% of voltage drop on Ut) per 0,5 cycles. 0% Ut (100% of voltage drop on Ut) per 1 cycles. 70% Ut (30% of voltage drop on Ut) per 25/30 cycles. 0% Ut (100% of voltage drop on Ut) per 250/300 cycles.	0% Ut 100% of voltage drop on Ut) per 0,5 cycles. 0% Ut (100% of voltage drop on Ut) per 1 cycles. 70% Ut (30% of voltage drop on Ut) per 25/30 cycles. 0% Ut (100% of voltage drop on Ut) per 250/300 cycles.	Mains supply shall have the quality used in typical commercial or hospital environment. If the user of the IVL Generator requires continuous operation during a power outage, it is recommended that the IVL Generator be powered by an uninterrupted power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be of the quality typical for use in a commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside the ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	3 Vrms 150 kHz to 80 MHz outside the ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	It is recommended that portable or mobile RF communications equipment not be used in close proximity to any part of the Coronary Intravascular Lithotripsy (IVL) Catheter including cables, with separation distance less than recommended, calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80MHz to 800MHz $d=2.3\sqrt{P}$ 800MHz to 2.5GHz Where P is the maximum rated output power of the transmitter in

Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.5GHz	Not applicable	Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). It is recommended that the established field strength of the RF transmitter, as determined by an electromagnetic site survey, be less than the compliance level in each frequency band. Interference may occur around equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800MHz, the higher frequency range applies. NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
A The ISM (industrial, medical and scientific) bands between 150KHz and 80MHz are 6.765MHz to 6.795MHz; 13.553MHz to 13.567MHz; 26.957Mhz to 27.283MHz; and 40.66Mhz to 40.70MHz. B Compliance levels in the ISM frequency bands between 150KHZ and 80MHz and in the frequency band between 80MHz to 2.5GHz are intended to reduce the likelihood of mobile and portable communications equipment causing interference if it is inappropriately translated to the patient environment. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. C The field strengths established by fixed transmitters such as base stations, telephone (cellular/cordless) land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended to consider an electromagnetic site survey. If the field strength measurement at the location where the Coronary Intravascular Lithotripsy (IVL) Catheter is used exceeds the applicable RF compliance level above, the Coronary Intravascular Lithotripsy (IVL) Catheter should be observed to verify that operation is Normal. If abnormal performance is observed, additional procedures may be required, such as re-orienting or relocating the Coronary Intravascular Lithotripsy (IVL) Catheter. D Above the frequency range of 150kHz to 80 MHz, the field strength should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communication equipment and equipment			
Coronary Intravascular Lithotripsy (IVL) Catheter is intended to be used in electromagnetic environments where radiated RF disturbance is controlled. The purchaser or user of a Coronary Intravascular Lithotripsy (IVL) Catheter may protect against electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication equipment (transmitter) and the equipment, depending on the maximum power output of the communication equipment.			
Rated maximum power output of transmitter (W)	Separation distance corresponding to different frequencies of transmitter (m)		
	150 kHz to 80MHz $d=1.2\sqrt{P}$	80MHz to 800MHz $d=1.2\sqrt{P}$	800MHz to 2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23

0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters with a maximum output power rating not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transformer in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Manufacturer: Spectrumedics Medical Technology (Shanghai) Co., Ltd
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Note:

Summary of Safety and Clinical Performance (SSCP):

The SSCP is available in the European database on medical devices (Eudamed) and linked to the basic UDI-DI.

The summary of safety and clinical performance can be downloaded from the following website: https://ec.europa.eu/tools/eudamed.

The value of the basic UDI-DI is 697492982SWCAY2