

INSTRUCTIONS FOR USE

NeoChord™ Artificial Chordae Delivery System
Model DS1000™

For Export Only

NeoChord

NeoChord, Inc.

5402 Parkdale Drive, Suite 160

St. Louis Park, Minnesota 55416, U.S.A.

Phone: (952) 698 7800

NEOCHORD and the stylized NeoChord logo are registered trademarks of the NeoChord Corporation.

1. **CONTENTS**

- (1) Delivery System
- (2) Cartridges
- (2) Needles

Device IEC 60601-1 Classification:

The DS1000 is DC internally powered, 3.0 VDC 420 mA Max.
Type CF applied part IPX0



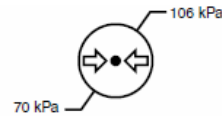
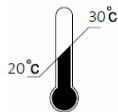
2. **DEVICE DESCRIPTION**

The NeoChord DS1000 is a single-use, hand-held device designed to deploy artificial chordae through a minimally invasive incision that accesses the mitral valve through the left ventricle while the heart is beating. The DS1000 deploys artificial chordae using commercially available ePTFE suture material, labeled for use as artificial chordae tendinae. The NeoChord DS1000 is an integrated modular system consisting of a hand-held delivery instrument, a cartridge in which ePTFE suture is loaded, a needle, and a tethered Leaflet Capture Verification monitor (LCV) that enables confirmation of capture of the free edge of the mitral leaflet in the distal clamp of the delivery instrument prior to deploying the ePTFE suture and knot at the leaflet.

The system is supplied sterile in disposable packaging.

3. **ENVIRONMENTAL SPECIFICATIONS**

Operating Conditions:



4. **INTENDED USE**

Repair of chordal elongation and rupture resulting in mitral valve prolapse.

INDICATIONS

Indicated for use in patients with Grade 3+ or 4+ mitral valve regurgitation who are candidates for surgical mitral valve repair or replacement.

CONTRAINDICATIONS

- Heavily calcified valves
- Valvular retraction with severely reduced mobility
- Active bacterial endocarditis
- Complex mechanism of MR (leaflet perforation, etc.)
- Significant tethering of leaflets
- Inflammatory valve disease

CAUTION: The NeoChord DS1000 has not been studied in patients with functional mitral regurgitation.

CAUTION: The NeoChord DS1000 has not been studied in patients with anterior leaflet prolapse.

WARNING: Patients who exhibit evidence of fragile tissue (e.g., severely dilated left ventricle, cachexia) may not be appropriate candidates for this surgery.

5. **WARNINGS**

- Use of the NeoChord DS1000 should be limited to physicians that have received training on the use of the device.
- Use of the device requires a minimum of one trained physician / operator and one trained member of the operating room staff.
- The NeoChord DS1000 is sterilized using EtO and is for single use only. Do not reuse or resterilize. Attempts to reuse or resterilize the device may result in patient harm, device malfunction, or inadequate sterilization.
- To avoid serious eye injury do not look directly into LED lumens at distal tip of the device.
- The NeoChord DS1000 is not suitable for use in the presence of flammable anesthetic mixture with air, oxygen nor nitrous oxide.
- The NeoChord DS1000 is not defibrillation proof and must be removed from the patient if defibrillation of the heart is required.
- The NeoChord DS1000 is not designed, nor should an attempt be made, to connect the system with any endoscopic devices.
- To minimize risks associated with the use of electrically powered devices during surgical procedures, ensure all devices are conformant with the relevant IEC and ISO standards and that their use is in accordance with Clause 16 of IEC 60601-1:2012.
- Do not attempt to tether the Leaflet Capture Verification monitor onto any high voltage devices within the operating room.
- After use of the NeoChord DS1000, dispose of all elements of the device, including cartridges, needles and Leaflet Capture Verification monitor in accordance with accepted institutional practice and in compliance with applicable laws and regulations including those pertaining to biohazardous material, needles and device batteries.

6. **PRECAUTIONS**

- The NeoChord DS1000 should be used in accordance with the necessary safety precautions appropriate to a thoracic device implantation procedure.
- Inspect package prior to use. Do not use any component of the system if damage to the sterile package is noted. Inspect all components prior to use. Do not use damaged, expired or non-sterile components.
- Do not use a device that has been dropped from a height of greater than eighteen (18) inches.
- The NeoChord DS1000 is to be used with ePTFE suture material that have an indication for use to repair or replace native chordae tendinae and which have a mean diameter of 0.307mm (e.g. GORE™ CV-4) or 0.246mm (e.g. GORE™ CV-5) only. Do not use the DS1000 with other suture materials or sizes as the compatibility of the DS1000 with other suture material and sizes is not known.

7. **POTENTIAL ADVERSE EVENTS**

The potential risks associated with the use of the NeoChord DS1000 System include the following:

- Air embolism
- Allergic reaction
- Arrhythmias
- Bleeding (with or without requiring transfusion)
- Broken ribs
- Conversion to standard valve repair surgery
- Damage to cardiovascular or nervous tissue
- Infection
- Failure to deliver ePTFE artificial chord to intended leaflet site
- Mitral regurgitation (>3)
- Mitral valve injury
- Pericardial damage
- Peripheral embolism
- Pulmonary embolism
- Stroke (CVA) or TIA

The potential risks associated with the general cardiac surgery include the following:

- Angina
- Allergic reaction (anesthetic)
- Cardiac arrest
- Cardiac perforation
- Cardiac tamponade
- Death
- Dilation of heart
- Drug reactions to antiplatelet / anticoagulation agents / contrast media
- Emergency cardiac surgery
- Endocarditis
- Heart Failure
- Hemolysis
- Hematoma
- Hypertension / hypotension
- Mitral stenosis
- Myocardial infarction
- Outflow tract obstruction
- Prolonged ventilation time
- Renal compromise
- Re-operation
- Septicemia
- Thrombosis
- Wound dehiscence

8. **ANCILLARY EQUIPMENT REQUIRED FOR THE PROCEDURE**

In addition to the standard equipment used for lateral thoracotomy, anesthesia and procedural patient monitoring, the NeoChord DS1000 procedure requires the use of the following equipment:

- Trans-Esophageal Echocardiography (TEE)
- Commercially available ePTFE suture indicated for chordae tendinae repair or replacement with a mean diameter of 0.307mm (e.g. GORE™ CV-4) or 0.246mm (e.g. GORE™ CV-5)
- Standard prolene suture
- Pledget
- Rubber-shod clamps

Additional Recommended Ancillary Equipment:

- Saline rinse tray

9. **DIRECTIONS FOR USE**

9.1. PRE-OP PATIENT MANAGEMENT / PLANNING:

9.1.1. Prophylactic antibiotic therapy is recommended, with dosage as dictated by institutional protocols for implantable surgical devices.

NOTE: Antiarrhythmics can be continued in cases of existing arrhythmias and can be used operatively per institutional protocol.

NOTE: Discontinuation of antiplatelet therapy is not required.

9.2. PREPARATION:

9.2.1. Ensure standards of room cleanliness and aseptic procedures are sufficient to assure device and procedural sterility.

9.2.2. Conduct aseptic skin preparation at access site using suitable technique.

NOTE: Patient draping is recommended.

9.2.3. Minimize patient discomfort utilizing standard sedation and local analgesia.

9.2.4. Perform a TEE examination of the mitral valve to:

9.2.4.1. Confirm that the patient does not have functional or ischemic mitral regurgitation.

9.2.4.2. Assess the width and location of the prolapsing leaflet segment to pre-operatively determine the appropriate number and placement location of artificial chordae. If patient anatomy allows, multiple chords should be placed in the prolapsing segment for maximum durability of the repair.

WARNING: Artificial chordae placed more laterally towards the pericommissural region may cause damage to or interfere with the native chordae.

9.2.5. Insert monitoring lines via standard procedures.

NOTE: Basic physiologic monitoring (EKG and aortic pressure) is recommended.

9.2.6. Open the NeoChord DS1000 Device pouches using standard sterile handling procedures.

9.3. IMPLANTATION PROCEDURE:

The NeoChord DS1000 procedure occurs in five steps: (i) Device Preparation; (ii) Left Ventricular Access; (iii) Leaflet Capture and Verification; (vi) Suture Deployment and (v) Suture Closure.

The sutures are placed via a ventriculotomy 2-4 cm postero-lateral from the apex of the left ventricle via thoracotomy.

WARNING: To avoid potential damage to or interference with the subvalvular apparatus including native chordae, the LV entry site should be in the postero-lateral LV wall rather than anterior.

9.4. Device Preparation

NOTE: A commercially available expanded polytetrafluoroethylene (ePTFE) suture indicated for chordae tendinae repair or replacement with a mean diameter of 0.307mm (e.g. GORE™ CV-4) or 0.246mm (e.g. GORE™ CV-5) is necessary to prepare the device. If the suture is provided from the manufacturer with an attached needle, remove the needle using a standard operating room sterile scissors cutting as close to the needle attachment point as possible. Dispose of needle(s) in Sharps Disposal or Destruction container.

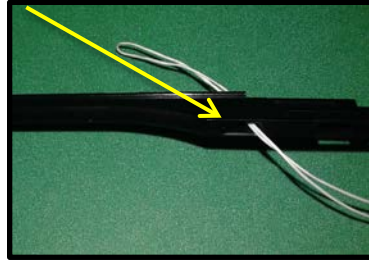
CAUTION: Do not damage the suture while removing the needle.

9.4.1. Test the device to ensure that the fiber optics are functioning properly by pushing the power button located on the Leaflet Capture Verification monitor.

NOTE: For proper battery management, the device should be turned off when not attempting leaflet capture.

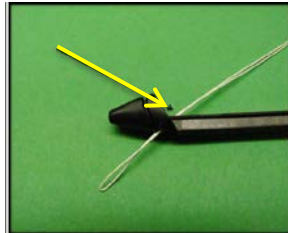
CAUTION: Do not attempt to replace the batteries contained within the device. If the device does not function as expected obtain a new system.

9.4.2. Locate the center of the ePTFE suture and create a gentle fold using care to not damage the suture. Holding the NeoChord DS1000 cartridge assembly in one hand with the distal clamp pointed toward the ceiling; thread the folded end of the ePTFE suture through the proximal opening on the underside of the cartridge assembly.

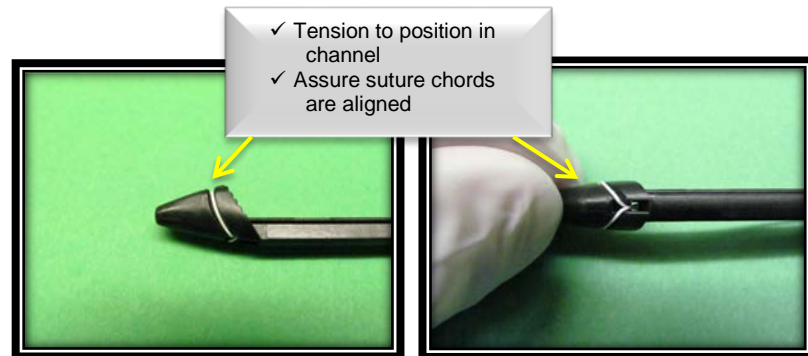


9.4.3. Draw the folded end of the suture along the groove in the cartridge assembly to the distal end, just proximal to the clamp used to secure the mitral valve during the procedure.

9.4.4. Thread the folded end through the opening at the end of the groove in the cartridge assembly.



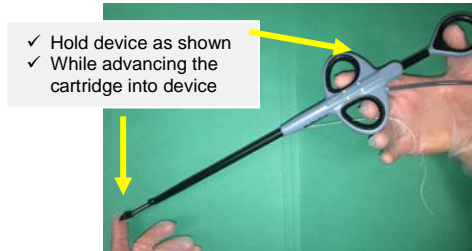
9.4.5. Separate the two halves of the suture at the fold and draw the loop over the head of the clamp, securing it in the groove proximal to the distal end of the device. Ensure that the loop over the head of the clamp is not twisted.



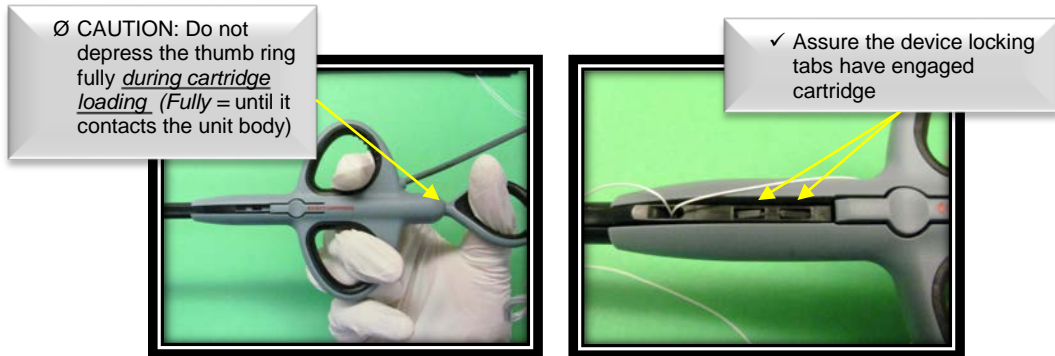
9.4.6. Pull the ends of the suture so the suture is loaded securely onto the cartridge assembly.

9.4.7. Place a rubber shod clamp on the free ends of the suture to assist in retaining the suture in the channel.

9.4.8. Select the handle from the sterile packaging and align the proximal end of the cartridge assembly with the distal end of the handle. The cartridge assembly and handle are grooved to create a channel for attachment. Slide the cartridge assembly into the handle. Advance the cartridge assembly until an audible snap is heard.



9.4.9. Once the audible snap is heard, gently depress on the thumb ring with one hand while you continue to advance the cartridge assembly until a second audible snap is heard. The cartridge is properly loaded and locked in position.



9.4.10. At this time, load a needle into the cartridge by selecting one of the needles from the sterile packaging. Grasping the needle at the proximal end, gently guide the needle into the groove at the top of the handle until the needle is in the start position.



CAUTION: Do not squeeze the handles of the needle together during device preparation.



WARNING: Do not advance the needle tip through the opening on the distal end of the device during loading. The needle must remain completely within the device until after leaflet capture.

9.4.11. Thoroughly rinse the needle and delivery system in sterile heparinized saline making sure to keep the LCV monitor dry and out of the saline.

9.4.12. The device is now ready for use.

9.5. Left Ventricular Access:

9.5.1. Define the thoracic anatomy using x-ray and echo.

9.5.2. Identify relevant landmarks such as cardiac silhouette, intercostal spacing and diaphragm.

9.5.3. Determine appropriate site for and complete lateral thoracotomy.

9.5.4. Expose apex of heart.

9.5.5. Determine the LV entry site. The LV entry site should be slightly displaced 2-4 cm from the apex of the left ventricle towards the postero-lateral LV free wall.

WARNING: To avoid potential damage to or interference with the subvalvular apparatus including native chordae, the LV entry site should be in the postero-lateral LV wall rather than anterior.

NOTE: Artificial chordae secured to this area will assume a more natural orientation inside the LV and will exit close to the base of the posterior papillary muscle. More importantly, this will ensure the artificial chordae will not cross the A-P midline of the mitral valve intercommissural plane.

9.5.6. A purse-string suture should be used at the site of the left ventricular apical access to control blood loss.

9.5.7. Make a small incision in the LV free wall 2-4 cm postero-lateral from the apex of the heart to allow access of the device.


9.5.8. Insert the device through the ventriculotomy into the left ventricle.

NOTE: Insertion of the device should be done using transesophageal echocardiography (TEE) to guide the surgeon.

WARNING: Do not advance the device into the left ventricle without TEE visualization.

9.5.9. While the heart is beating and under TEE visualization, advance the tip of the device to the mitral valve, passing the tip of the device approximately 4mm beyond the leaflets and into the left atrium.

9.6. Leaflet Capture and Verification

9.6.1. Once the device is across the mitral valve orifice, turn the power on by pressing the power button .

NOTE: Device will operate continuously for one hour once button is pressed.

9.6.2. The clamp should be opened by advancing the thumb ring towards the distal end of the device.

9.6.3. The tip of the device should be used to guide the flailing leaflet into the open clamp.

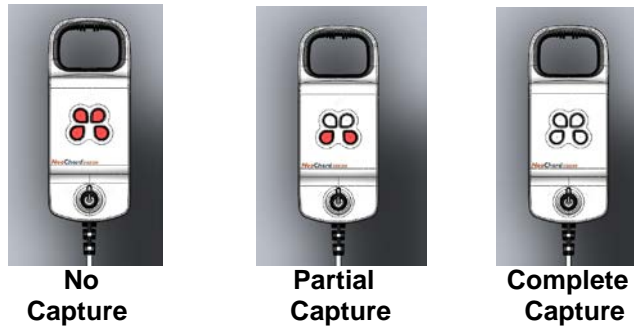
WARNING: Beware of possible interference with the subvalvular apparatus.

WARNING: Artificial chordae placed more laterally towards the pericommissural region may cause damage to or interfere with the native chordae.

9.6.4. Gently close the clamp by retracting the thumb ring toward the user.

9.6.5. Confirmation of leaflet capture is accomplished by examining the fiber optic display. Four white lights on the monitor display confirm that leaflet tissue is captured within the distal clamp.

CAUTION: If any light is illuminated red, release the leaflet and repeat this step.



9.7. Suture Deployment

9.7.1. Visualize the mitral valve using TEE and confirm that all fiber optic indicators are still white.

NOTE: Maintain back pressure on thumb ring during needle advancement.

9.7.2. Advance the needle by grasping the needle handle and compressing the needle handle tabs.

9.7.3. Advance the needle to the fully advanced position marked on the body of the instrument.

9.7.4. Simultaneously, with the rubber shod clamp holding tension on the suture, maintain back pressure on thumb ring and retract the needle until engagement of the suture is detected. At this point, release the rubber shod clamp and continue to retract the needle in a smooth continuous motion until the distal tip of the needle and suture loop exit the instrument.

NOTE: Make sure the needle is pulled straight back, parallel to the instrument without bending.

NOTE: Instrument clamp must remain closed during needle retraction.

9.7.5. Carefully, disengage the needle from the suture and return the needle to the sterile area.

9.7.6. Open the instrument clamp and release the captured leaflet. Close the clamp and exit the left ventricle while guiding the two ends of the suture material from the instrument. The Leaflet Capture Verification monitor should be turned off.

9.7.7. Thread a prolene suture through the loop end of the ePTFE suture.

NOTE: The prolene suture is only for use in ePTFE suture retrieval procedure after tensioning if necessary.

9.7.8. Take the two free ends of the ePTFE suture and pass them through the loop end of the ePTFE to create a girth hitch on the leaflet. Pull the ePTFE girth hitch tight.

9.7.9. Test the ePTFE suture placement to assure optimal MR reduction. This is completed by tensioning the suture and monitoring MR reduction on the TEE monitor.

9.7.10. If the suture deployment is unsatisfactory, pull gently on the prolene suture to retrieve the ePTFE suture. Discard both the prolene and ePTFE suture.

WARNING: Prior to loading the device to deploy a second suture, thoroughly rinse the needle, cartridge and delivery system in sterile heparinized saline.

- Ensure components are completely rinsed to remove blood from all areas, particularly suture channels, distal tip fiber optics, cartridge, and slider bar.
- Visually inspect the needle tip to ensure it is straight and has not been bent or damaged. Do not reuse the needle if the tip has been bent or damaged.
- Keep the LCV monitor dry and out of the saline.

9.7.11. If placement of additional suture(s) is desired, repeat steps 9.4.2 - 9.7.10.

NOTE: If patient's anatomy allows, multiple chords should be placed in the prolapsing segment for maximum durability of the repair.

9.8. SUTURE CLOSURE

9.8.1. Under TEE or TTE visualization, determine the appropriate length for the ePTFE chord(s) to minimize residual MR.

WARNING: Prior to final anchoring of the artificial chordae, assess for any involvement of the anterior leaflet with the artificial chordae. If any artificial chordae appears to have potential interference with the native anterior chordae, the artificial chordae should be removed to prevent potential damage or rupture of the native chordae.

NOTE: Ideally, three (3) double chordae should be implanted, and each double chordae, when tensioned, should be able to significantly reduce MR to at least mild-to-moderate.

NOTE: Any chordae that fails to be able to independently reduce MR should be removed and replaced.

9.8.2. If the suture deployment is satisfactory, remove and discard each prolene suture.

9.8.3. If suture deployment is unsatisfactory pull gently on the prolene suture to retrieve the ePTFE suture. Discard both the prolene and ePTFE suture. If placement of additional suture(s) is desired, repeat steps 9.4.2 - 9.7.10.

9.8.4. When the appropriate length has been determined, secure the suture(s) on the epicardium adjacent to the ventriculotomy using a standard knot and pledget. It is recommended to secure each suture individually to the large purse string pledget at the ventriculotomy site which provides a wide base of support.

CAUTION: Each suture should be anchored independently to a large pledget to prevent potential gradual shifting of the anchored artificial chordae which may result in loosening of the artificial chordae post-operatively.

WARNING: Once the suture has been secured to the epicardium the artificial chordae can no longer be removed without surgical (open heart) intervention.

9.8.5. Close the incision area as appropriate.

10. POSTOPERATIVE CONSIDERATIONS

Patients who receive at least one artificial chordae using the NeoChord DS1000 should be managed per the normal standard of care for cardiac implants. As such, a standard anticoagulation regimen for similar cardiac implants such as an annuloplasty ring is recommended. Antibiotic administration is recommended per institutional protocol for cardiovascular implant procedure. Patient monitoring via telemetry should be continued as necessary.


11. ELECTROMAGNETIC COMPLIANCE

The DS1000 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 201: Guidance and manufacturer's declaration – electromagnetic emission – for all equipment and systems.

Guidance and manufacturer's declaration – electromagnetic emissions		
The DS1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the DS1000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DS1000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 204: Guidance and manufacturer's declaration – electromagnetic immunity – for equipment and systems that are not life supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The DS1000 is intended for use in the electromagnetic environment specified below. The customer or the user of the DS1000 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conduct RF IEC 61000-4-6	3 V/m 80 MHz to 2.5 GHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the DS1000 system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from mixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3		[E ₁] V/m	
NOTE 1 At 80 MHz and 800 MHz, 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.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DS1000 is used exceeds the applicable RF compliance level			

Guidance and manufacturer's declaration – electromagnetic immunity

above, the DS1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DS1000.

^b Over the frequency range 150 kHz, field strengths should be less than $[V_1]$ V/m.

12. **STORAGE**

Store devices in a cool, dark, dry place.























13. **WARRANTY AND LIMITATIONS**

NeoChord, Inc. warrants that each component of this system has been manufactured packaged and tested with reasonable care and will be free from defects in workmanship and material. NeoChord, Inc. will not be liable for any incidental, special or consequential loss, damage or expense, direct or indirect, from the use of its product. NeoChord's sole obligation shall be to repair or replace at its option, any device that we feel was defective at time of shipment if notice thereof is received within six (6) months. User assumes all liability, whether arising on warranty, contract, and negligence or otherwise for damages resulting from the handling, possession, use or misuse of the product. Because NeoChord has no control over the operation, inspection, maintenance or use of its products after distribution and has no control over the selection of patients, THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND OF ANY OTHER OBLIGATION ON THE PART OF THE SELLER. The remedies set forth in the Warranty and Limitation shall be the exclusive remedy available to any person. No agent, employee or representative of NeoChord has any authority to change any of the foregoing or assume or bind NeoChord to any additional liability or responsibility in connection with this device.

14. **SYMBOL DEFINITIONS**

The following symbols appear on the device packaging and labeling:

Symbol	Description	Symbol	Description
	Consult Operating Instructions		Type CF Equipment
	Power Button		Sterilized using ethylene oxide
	Manufacturer		Not for General Waste
	Serial Number		Single use only
	Batch Code		Do not use if package is damaged
	Catalogue Number		EU authorized representative
	Keep dry		Store in cool place
	Date of Manufacture		Non-ionized radiation
	Use by Date		Atmospheric pressure limitation
	Temperature limitation		Humidity limitation

Authorized Representative:

PSF Medical BV
Marten Meesweg 8-10
3068 AV Rotterdam
The Netherlands

DS1000 Part Number:
500000-002

