UNiS

PICC(Peripherally Inserted Central Catheter)

GENOSS

MS-P2251/IFU-DS1706(Rev.8,2407)

UNIS PICC (Peripherally Inserted Central Catheter)

PRODUCT DESCRIPTION

Unis PICC is a tube-shaped catheter with polyurethane material. This product is inserted into a patient's blood vessel and used for infusion of drugs and fluids, blood collection, and transfusion through hubs. It is inserted through the antecubital fossa or upper arm of the peripheral blood vessel, and is slowly inserted through the introducer until it is located in the superior vena cava, and the end of the catheter inserted into the patient is located in the center of the superior vena cava, delivering parenteral therapies directly to the central venous system. It is a multiple lumen catheter with up to three incompatible lumen and has radiopaque capability to facilitate positioning in fluoroscopy. In addition, Unis PICC comprises a total of eight types of Accessary, including the function kit.

Table 1. Catheter specifications

Model	French size (Outer Diameter)	Lumens	Gauge size (inner Diameter)	Catheter length (cm)	Maximum flow rate (with warmed contrast)	Priming volume	Guide wire length (cm)
GP-4SIR	4 Fr	1	18	55	5 mL / sec	< 0.67 mL	120
GP-5SIR	5 Fr	1	18	55	5 mL / sec		120
GP-5DIR	5 Fr	2	18 / 18	55	5 mL / sec	< 0.8 mL	120
GP-5TIR	5 Fr	3	18 / 19 / 19	55	5 mL / sec		120
GP-6DIR	6 Fr	2	17 / 17	55	6 mL / sec	< 1.0 mL	120
GP-6TIR	6 Fr	3	17 / 19 / 19	55	6 mL / sec		120
GP-4SIR70	4 Fr	1	18	55	5 mL / sec	< 0.67 mL	70
GP-5SIR70	5 Fr	1	18	55	5 mL / sec		70
GP-5DIR70	5 Fr	2	18 / 18	55	5 mL / sec	< 0.8 mL	70
GP-5TIR70	5 Fr	3	18 / 19 / 19	55	5 mL / sec		70
GP-6DIR70	6 Fr	2	17 / 17	55	6 mL / sec	< 1.0 mL	70
GP-6TIR70	6 Fr	3	17 / 19 / 19	55	6 mL / sec		70

INDICATIONS

The Unis PICC is indicated for short or long term peripheral access to the central venous system for intravenous therapy, power injection of contrast media, and allows for central venous pressure monitoring. For blood sampling, infusion, or therapy use a 4 French or larger catheter. The maximum recommended infusion rate is 5 mL/sec for power injection of contrast media.

CONTRAINDICATIONS

The device is contraindicated whenever:

The presence of device-related infection, bacteremia, or septicemia is known or suspected.
The patient's body size is insufficient to accommodate the size of the implanted device.
The patient is known or is suspected to be allergic to materials contained in the device.
Past irradiation of prospective insertion site.
Previous episodes of venous thrombosis or vascular surgical procedures at the prospective placement site.
Local tissue factors will prevent proper device stabilization and/or access.

WARNINGS

General Warnings

When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/ or povidone iodine are the suggested antiseptics to use.
Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
Do not use the catheter if there is any evidence of mechanical damage or leaking. Damage to the catheter may lead to rupture, fragmentation, possible embolism and surgical removal.
If signs of extravasation exist, discontinue injections. Begin appropriate medical intervention immediately.
Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.
Intended for Single Patient Use. DO NOT REUSE. The Unis PICC is a single use device and should never be re-implanted. Reuse carries with it the attendant concern of cross-infection regardless of the cleaning or sterilization method. Re-sterilization of incompletely cleaned devices may not be effective. Any device that has been contaminated by blood must not be reused or re-sterilized.
The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.

Placement Warnings

If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.
This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.
Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and/or risk of patient injury.

Power Injection Warnings

Exceeding the maximum flow rate of 5 mL/sec, or the maximum pressure of power injectors of 300 psi, may result in catheter failure and/or catheter tip displacement. Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
Power injector machine pressure limiting feature may not prevent over-pressurization of an occluded catheter, which may cause catheter failure.
The UnisTM PICC indication for power injection of contrast media implies the catheter's ability to withstand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

PRECAUTIONS

General Precautions

Sterilized by ethylene oxide. Do not re-sterilize.

Carefully read and follow all instructions prior to use.
After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.
Only qualified health care practitioners should insert, manipulate and remove these devices.
Follow Universal Precautions when inserting and maintaining the catheter.
Follow all contraindications, warnings, cautions, precautions and instructions for all infusates, including contrast media, as specified by their manufacturer.
Precautions are intended to help avoid catheter damage and/or patient injury.
Use aseptic techniques whenever the catheter lumen is opened or connected to other devices.
Examine the package carefully before opening to confirm its integrity and that the expiration date has not passed. The device is supplied in a sterile package and is non- pyrogenic. Do not use if package is damaged, opened or the expiration date has passed. Inspect kit for inclusion of all components.
Accessories and components used in conjunction with this device should incorporate luer lock connections.
Do not use a syringe smaller than 10 ml to flush and confirm patency. Patency should be assessed with a 10 mL syringe or larger with sterile normal saline. Upon confirmation of patency, administration of medication should be given in a syringe appropriately sized for the dose. Do not infuse against resistance.
Prolonged infusion pressure greater than 25 psi may damage blood vessels or viscus. Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparin flush solution.
As reported in literature, anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement, positioning, flushing of central venous catheters or cleaning of catheter exit site. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.

Precautions Related to Device Placement Procedure

The Unis PICC features a reverse-taper catheter design. Placement of larger catheters at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the Unis PICC above antecubital fossa is recommended.
Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
Flush the catheter with sterile normal saline prior to use. Catheter stylet must be wetted prior to stylet repositioning or withdrawal.
Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods.
If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
Never use force to remove the stylet. Resistance can damage the catheter. If resistance or bunching of the catheter is observed, stop stylet withdrawal and allow the catheter to return to normal shape. Withdraw both the catheter and stylet together approximately 2 cm and reattempt stylet removal. Repeat this procedure until the stylet is easily removed. Once the stylet is out, advance the catheter into the desired position. Avoid accidental device contact with sharp instruments and mechanical damage to the catheter material. Use only smooth-edged atraumatic clamps or forceps. Avoid perforating, tearing or fracturing the catheter when using a guidewire. Avoid sharp or acute angles during implantation which could compromise the patency of the catheter lumen.
Do not use scissors to remove dressing to minimize the risk of cutting catheter.
Do not suture through or around any part of the catheter's tubing (shaft or extension legs).
If using sutures to secure catheter USE THE SUTURE WINGS and make sure they do not occlude, puncture, or cut the catheter.
The catheter must be secured in place to minimize risk of catheter breakage and embolization.
To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of saline.
Do not withdraw dilator from microintroducer sheath until sheath is within vessel to minimize the risk of damage to sheath tip.
Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.
Do not cut guidewire to alter length.
Do not insert stiff end of guidewire into vessel as this may result in vessel damage.
Keep sufficient guidewire length exposed at hub to allow for proper handling. Anon- controlled guidewire can lead to wire embolism.
Do not use excessive force when introducing guidewire or microintroducer as this can lead to vessel perforation and bleeding.
Never leave stylet or stiffening wire in place after catheter insertion; injury may occur. Remove stylet or stiffening wire and T-lock (as applicable) after insertion.
The stylet or stiffening wire needs to be well behind the point the catheter is to be cut.
NEVER cut the stylet or stiffening wire.
Do not reinsert needle into IV catheter to minimize the risk of the needle damaging or shearing the IV catheter.
Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.

POSSIBLE COMPLICATIONS

The potential exists for serious complications including the following

Air Embolism	Hematoma	Myocardial Erosion
Bleeding	Heparin Induced Thrombocytopenia	Perforation of Vessels or Viscus
Brachial Plexus Injury	Hypersensitivity, anaphylactic or anaphylactic-like reaction during placement, positioning, flushing of catheter or cleaning of catheter exit site	Phlebitis
Cardiac Arrhythmia		Spontaneous Catheter Tip Malposition or Retraction
Cardiac Tamponade		Thromboembolism
Catheter Erosion Through the Skin		Venous Thrombosis
Catheter Embolism		Vessel Erosion
Catheter Occlusion		Risks Normally Associated with Local or General Anesthesia, Surgery, and Post-Operative Recovery
Catheter Related Sepsis		
Endocarditis		
Exit Site Infection	Intolerance Reaction to Implanted Device	
Exit Site Necrosis		
Extravasation	Laceration of Vessels or Viscus	
Fibrin Sheath Formation		

INSERTION INSTRUCTIONS

Identify the Vein and Insertion Site

1) Apply a tourniquet above the anticipated insertion site.
2) Select and mark the vein based on patient assessment. Recommended veins are basilic, cephalic and median cubital veins.
   Caution: The Unis PICC features a reverse-taper catheter design. Placement of larger catheter at or below antecubital fossa may result in an increased incidence of phlebitis. Placement of the Unis PICC above antecubital fossa is recommended.
   Caution: Avoid placement or securement of the catheter where kinking may occur, to minimize stress on the catheter, patency problems or patient discomfort.
3) Release tourniquet.

Patient Position / Catheter Measurement

1) Position the arm at a 90° angle.
2) For central placement, the recommended target tip location is in the lower 1/3 of the Superior Vena Cava (SVC). Measure from the planned insertion site

to he right clavicular head, then down to the third intercostal space.
Note: The external measurement can never exactly duplicate the internal venous anatomy.

Skin Preparation

1) Don prep gloves.
2) Apply underdrape.
3) When alcohol is used as a skin prep, it must be allowed to completely air dry before proceeding with insertion.
4) Remove and discard gloves.

Sterile Field Preparation

1) Apply the tourniquet above the intended insertion site to distend the vessel.
2) Don sterile gloves.
3) Apply drapes and complete sterile field preparation.

Preflush the Catheter

1) Attach prefilled syringe to the luer attachment on the hub and flush catheter with sterile normal saline.
2) The syringe may be left attached during procedure.
Caution: Do not clamp extension leg when stylet or stiffening wire is in catheter to minimize the risk of component or catheter damage.

Modification of Catheter Length

Note: Catheters can be cut to length if a different length is desired due to patient size and desired point of insertion according to hospital protocol. Catheter depth markings are in centimeters.
WARNING: For the UnisTM PICC, do not trim the catheter shorter than 30 cm. Trimming
shorter than 30 cm could result in catheter tip displacement while power injecting.

1) Measure the distance from the insertion site (zero mark) to the desired tip location.
2) Using a sterile scalpel or scissors, carefully cut the catheter according to institutional policy if necessary.
Caution: The stylet or stiffening wire needs to be well behind the point the catheter is to be cut. NEVER cut the stylet or stiffening wire.
3) Inspect cut surface to assure there is no loose material.
4) Assure proper alignment of the stylet to the distal end of the trimmed catheter.

Perform Venipuncture

1) Anesthetize with local anesthesia as required.
2) Remove the needle guard.
3) Insert the safety introducer needle into the desired vein and observe for flashback.
WARNING: If the artery is entered, withdraw the needle and apply manual pressure for several minutes.
4) Release tourniquet.
5) Remove the guidewire tip protector from the guidewire hoop and insert the flexible end of the guidewire into the introducer needle and into the vein. Advance the guidewire to the desired depth.
Caution: Do not advance the guidewire past the axilla without fluoroscopic guidance or other tip locating methods. Caution: Do not use excessive force when introducing guidewire or micro-introducer as this can lead to vessel perforation and bleeding.
6) Gently withdraw and remove the safety introducer needle, while holding the guidewire in position. Caution: If the guidewire must be withdrawn while the needle is inserted, remove both the needle and wire as a unit to prevent the needle from damaging or shearing the guidewire.
7) Advance the introducer assembly over the guidewire. Using a twisting motion, advance the assembly into the vessel. If necessary, a small incision may be made adjacent to the guidewire to facilitate insertion of the sheath and dilator. Verify institutional guidelines concerning the use of a safety scalpel prior to making incision.
8) Withdraw the dilator and guidewire, leaving the small sheath in place.
WARNING: Place a finger over the orifice of the sheath to minimize blood loss and risk of air aspiration. The risk of air embolism is reduced by performing this part of the procedure with the patient performing the Valsalva maneuver until the catheter is inserted into the sheath.

INSERT AND ADVANCE THE CATHETER

1) Position the arm at a 90° angle, maintaining sterility.
2) Insert the catheter into the introducer sheath.
3) Advance the catheter slowly.

COMPLETE CATHETER INSERTION

1) Continue to advance the catheter. For central placement, when the tip has advanced to the shoulder, have the patient turn head (chin on shoulder) toward the insertion side to prevent possible insertion into the jugular vein.
Note: The Unis PICC features a reverse-taper catheter design. Resistance may be felt approximately 7cm distal of catheter hub when introducing the catheter into the sheath due to an increase in outer diameter (O.D.) The introducer may be partially split, but not removed to facilitate insertion of the catheter past this point if necessary.
2) Complete catheter advancement into the desired position.
Note: Maximum recommended insertion is to the zero mark on the catheter shaft.
Note: PICCs should be positioned with the catheter tip in the lower 1/3 of the Superior Vena Cava (SVC). Verify correct catheter tip position using radiography or other appropriate technology.
WARNING: This is not a right atrium catheter. Avoid positioning the catheter tip in the right atrium. Placement or migration of the catheter tip into the right atrium may cause cardiac arrhythmia, myocardial erosion or cardiac tamponade. The risk of these complications may be more likely in neonatal patients.

RETRACT AND REMOVE THE INTRODUCER SHEATH

1) Stabilize the catheter position by applying pressure to the vein distal to the introducer sheath.
2) Withdraw the introducer sheath from the vein and away from the site.Split the introducer sheath and peel it away from the catheter.
Caution: Do not pull apart the portion of the sheath that remains in the vessel. To avoid vessel damage, pull back the sheath as far as possible and tear the sheath only a few centimeters at a time.

ASPIRATE AND FLUSH

1) Attach primed extension set and/or saline-filled syringe. 2) Aspirate for adequate blood return and flush catheter with 10 mL normal saline to ensure patency.
Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of saline.
Caution: Anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement, positioning, flushing of central venous catheters or cleaning of catheter exit site. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
3) Cap catheter.
WARNING: The fluid level in the catheter will drop if the catheter connector is held above the level of the patient's heart and opened to air. To help prevent a drop in the fluid level (allowing air entry) while changing injection caps, hold the connector below the level of the patient's heart before removing the injection cap.

SECURING THE UNIS PICC

Caution: The catheter must be secured in place to minimize risk of catheter breakage and embolization.
WARNING: When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

WARNING: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.
WARNING: Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol-containing ointments. These can damage the polyurethane material if used over time.
The StatLock® catheter stabilization device may be included in Unis PICC kits. Please refer to Instructions For Use on the proper use and removal. The StatLock® catheter stabilization device should be monitored daily and replaced at least every seven days.

THE STATLOCK STABILIZATION DEVICE PROCEDURE

1) Secure catheter with Statlock catheter stabilization device.
2) Cover site and Statlock catheter stabilization device with transparent dressing
3) Place anchor tape sticky side up, under hub. Wedge tape between hub and wings.
4) Chevron anchor tape on top of transparent dressing.

VERIFY PLACEMENT

1) PICC should be positioned with the catheter tip in the lower 1/3 of the SVC. Verify correct catheter tip position using radiography or other appropriate technology.

POWER INJECTION PROCEDURE

WARNING: The Unis PICC indication for power injection of contrast media implies the catheter's ability to with stand the procedure, but does not imply appropriateness of the procedure for a particular patient. A suitably trained clinician is responsible for evaluating the health status of a patient as it pertains to a power injection procedure.

1) Remove the injection/needleless/end cap from the Unis PICC.
2) Attach a 10 mL or larger syringe filled with sterile normal saline.
3) Aspirate for adequate blood return and vigorously flush the catheter with the full 10 mL of sterile normal saline. This will ensure the patency of the Unis PICC and prevent damage to the catheter. Resistance to flushing may indicate partial or complete catheter occlusion. Do not proceed with power injection study until occlusion has been cleared.
   WARNING: Failure to ensure patency of the catheter prior to power injection studies may result in catheter failure.
4) Detach syringe.
5) Attach the power injection device to the Unis PICC per manufacturer' s recommendations.
6) Contrast media should be warmed to body temperature prior to power injection.
   WARNING: Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
7) Use only lumens marked "Power Injectable" for power injection of contrast media.
   WARNING: Use of lumens not marked "Power Injectable" for power injection of contrast media may cause failure of the catheter.
8) Complete power injection study taking care not to exceed the flow rate limits. Do not exceed the maximum flow rate of 5 mL/sec.
   WARNING: Exceeding the maximum flow rate of 5 mL/sec, or the maximum pressure of power injectors of 300 psi, may result in catheter failure and/or catheter tip displacement.
   WARNING: Power injector machine pressure limiting feature may not prevent over- pressurization of an occluded catheter, which may cause catheter failure.
9) Disconnect the power injection device.
10) Replace the injection/needleless/end cap on the Unis PICC.
11) Flush the Unis PICC with 10 mL of sterile normal saline, using a 10 mL or larger syringe.

SUGGESTED CATHETER MAINTENANCE

Caution: Anaphylactic or anaphylactic-like reactions occur in a small percentage of the population during placement, positioning, flushing of central venous catheters or cleaning of catheter exit site. These reactions are reported in association with insertion, rapid flushing, or manipulation of the catheter and/or use of chlorhexidine gluconate (CHG) in some patients. Be aware of the potential symptoms or signs of these reactions and take precautionary steps as dictated by institution protocol for their prevention or treatment.
Caution: If CHG allergy is suspected, confirmatory testing is recommended.

Dressing Changes/Exit Site Cleaning

Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.
Caution: Do not suture through or around any part of the catheter's tubing (shaft or extension legs). If using sutures to secure catheter USE THE SUTURE WINGS and make sure they do not occlude, puncture, or cut the catheter.
Caution: The catheter must be secured in place to minimize risk of catheter breakage and embolization.

1) Assess the dressing in the first 24 hours for accumulation of blood, fluid or moisture beneath the dressing. During all dressing changes, assess the external length of the catheter to determine if migration of the catheter has occurred. Periodically confirm catheter placement, tip location, patency and security of dressing.
   WARNING: Do not wipe the catheter with acetone-based solutions, tincture of iodine or polyethylene glycol- containing ointments. These can damage the polyurethane material if used over time
   WARNING: When using alcohol or alcohol-containing antiseptics with polyurethane PICCs, care should be taken to avoid prolonged or excessive contact. Solutions should be allowed to completely dry before applying an occlusive dressing. Chlorhexidine gluconate and/or povidone iodine are the suggested antiseptics to use.

Flushing

Caution: Some patients may be hypersensitive to heparin or suffer from heparin induced thrombocytopenia (HIT) and these patients must not have their catheter locked with heparin flush solution.

1) Flush each lumen of the catheter with 10 mL of saline every 12 hours or after each use. Use a 10 mL or larger syringe.
2) In addition, lock each lumen of the catheter with heparin flush solution. Usually, 1 mL per lumen is adequate.
3) Disconnect the syringe and attach a sterile end cap to the catheter hub and tighten securely.
4) Prior to blood sampling when infusing TPN, follow routine maintenance procedure except use 20 mL saline and flush to clear TPN from the catheter.
5) If resistance is met when flushing, no further attempts should be made. Further flushing could result in catheter rupture with possible embolization. Refer to institution protocol for clearing occluded catheters.
   NOTE: When injecting or infusing medications that are incompatible, you should always flush the catheter with a minimum of 10 mL saline before and after the medication.
   Caution: To reduce potential for blood backflow into the catheter tip, always remove needles or syringes slowly while injecting the last 0.5 mL of saline
   Caution: Use aseptic techniques whenever the catheter lumen is opened orconnected to other devices. WARNING: Alcohol should not be used to lock, soak or declot polyurethane PICCs because alcohol is known to degrade polyurethane catheters over time with repeated and prolonged exposure.

Occluded or Partially Occluded Catheter

Catheters that present resistance to flushing and aspiration may be partially or completely occluded. Do not flush against resistance. If the lumen will neither flush nor aspirate and it has been determined that the catheter is occluded with blood, a declotting procedure per institution protocol may be appropriate.

CATHETER REMOVAL

1) Remove dressing and StatLock catheter stabilization device or tape securement strips. Caution: Do not use scissors to remove dressing to minimize the risk of cutting catheter.
2) Grasp catheter near insertion site.
3) Remove slowly. Do not use excessive force.
4) If resistance is felt, stop removal. Apply warm compress and wait 20-30 minutes.
5) Resume removal procedure.
6) Examine catheter tip to determine that the entire catheter has been removed.

HOW SUPPLIED

Contents supplied STERILE using an ethylene oxide (EO) process. Store in a cool, dry, dark place. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Please see package label for additional storage conditions.

WARRANTY

GENOSS Co., Ltd. Warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Genoss Co., Ltd. is control directly affect the instrument and the results obtained from its use. Genoss Co., Ltd. is obligation under this warranty is limited to the repair or replacement of this instrument and Genoss Co., Ltd. shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Genoss Co., Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. Genoss Co., Ltd. assumes no liability with respect to instruments reuse d, reprocessed, resterilized, modified or altered in any way, and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.

SYMBOL

	Caution		Do not re-sterilize
	Sterilized using ethylene oxide		Do not use if package is damaged
	Temperature limit		Manufacturer
	Keep away from sunlight		Date of manufacture
	Keep dry		Use by date
	Do not re-use		Consult instructions for use
REF	Catalogue number	LOT	Batch code

CE 2195

EC REP **EMERGO EUROPE**
Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands

GENOSS Co., Ltd. Made in Korea
1F, Gyeonggi R&DB Center, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of KOREA
Tel. +82-31-888-5100 **Fax.** +82-31-888-5105 www.genoss.com