TraumaGuard Intra-abdominal Pressure-Sensing System

Instructions for Use

Please read the instructions before use

This pack contains:
4 x TraumaGuard Intra-abdominal Pressure-Sensing Catheter (Model No. 000-0221)

Product Description

TraumaGuard Intra-abdominal Pressure-Sensing Catheter ("TG"). TG is a urine drainage catheter that provides continuous biometric monitoring of Intra-abdominal Pressure ("IAP") and Core Body Temperature (CBT). TG is a silicone catheter with polyurethane sensing balloons.

TG has a urine drainage lumen, inflation channel, and an integrated retention balloon about five centimeters (5 cm) from the tip of the catheter. The catheter has an atraumatic tip with two (2) opposite drainage eyes in between the silicone and polyurethane balloons.

There are two (2) polyurethane balloons used to detect changes in IAP, the outer distal balloon and the inner sensing balloon. The outer balloon is filled with three cubic centimeters (3.0cc) of sterile water to ensure contact with the bladder wall. The inner sensing balloon has a column of air that runs the entire length of the catheter from the middle of the outer sensing balloon to a connector on the hub.

TG in conjunction with the TG Cable connects to standard hospital bedside monitors to record continuous IAP and CBT. Temperature can be displayed in Celsius or Fahrenheit and is accurate within one degree Celsius (±1°C) over a range of twenty-five to forty degrees Celsius (25°C to 40°C) [seventy-seven to one hundred four degrees Fahrenheit (77°F to 104°F)]. Pressure displayed is between zero to forty millimeters of mercury (0mmHg and 40mmHg) and is accurate within 3mmHg (±3mmHg). Refer to website link at the back of the IFU for monitor compatibility.

The inflation, drainage and sensing ports of the catheter are color-coded and can be operated with syringe.

Intended Use
TraumaGuard Intra-abdominal Pressure-Sensing System is intended for use in the drainage of urine and continuous measuring of intra-abdominal pressure (IAP) and core body temperature (CBT). The measured IAP can be used as an aid in the diagnosis of intra-abdominal hypertension ("IAH") and abdominal compartment syndrome ("ACS").

Intended Patient Population

IAP monitoring should be considered in any adult critically ill patient with risk factors for IAH/ACS.

Intended Users

Professional users: (healthcare professionals, clinicians, and assistants) with a medical degree, medical certification or nursing degree.

Contra-indications
TG should not be used if the patient has a known allergic reaction to silicone or polyurethane.

Important
Catheterization with TG can only be performed by a qualified and trained Healthcare Professional. TG is strictly single-use and must not be re-used. The TG Cable should be cleaned using the methods defined by local Clinical Policies.

Please Note

- Only use water-based lubricants or gels.
- Use a Luer Tip syringe to inflate the balloon with sterile water.
- Fill the balloon slowly to the specified capacity.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Precautions

- Use only under physician directive if any of the following Patient conditions are known to exist:
    - Known current Urinary Tract Infection (UTI)
    - Urethral injury and stricture
    - Recent urethral or bladder surgery
    - Prior transurethral resection of the prostate with a large tissue defect
    - History of abdominoperineal resection for rectal cancer, rectal stenosis, or other major rectal pathology
    - Significant symptoms of urinary obstruction prior to treatment
- Do not use ointments or lubricants with a petroleum base.
- Do not use sharp instruments with TG. Sharp instruments could damage the catheter and cause it to malfunction.
- It is recommended that the patient drink more water when catheterized – please follow local Clinical Policies on fluid intake.
- Patients with Indwelling Catheters should be monitored in accordance with local and national Clinical Policies.
- Strict adherence to aseptic technique and hand hygiene are essential to minimize the risk of Catheter-Associated Urinary Tract Infections.
- Do not stretch the catheter – stretching may damage the catheter.
- Do not modify or attempt to repair the TG cable. If malfunction occurs and is not resolved by following the procedure in step 3, discard and order a replacement unit.
- **Before opening the Catheter Package** visually inspect the integrity of the catheter package before aseptic presentation. Any damage to the packaging may mean the sterile barrier has been broken and may lead to patient infection.
- Do not re-use the sterile TG Catheter. Using a non-sterile catheter or reusing a single-use catheter significantly increases the risk of serious health complications, primarily infections.
- Check the connections for leaks on a regular basis. Should there be a leaking connection, this poses a risk of contamination or overdrainage.

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1) Monitor Connection

A. Connect the cable to the patient's bedside monitor.
B. Zero monitor to atmospheric pressure.
C. LED on cable will be blinking WHITE.

NOTE – If cable LED is blinking RED, disconnect cable from patient's bedside monitor and repeat steps A-B. If LED on cable is still blinking RED, DO NOT USE CABLE. Restart preparation steps using a different TG cable.

2) Preparation / Insertion

A. Attach a sterile drainage bag to TG drainage port.
B. With a 10cc Syringe attach to the WHITE port and retract plunger enough to evacuate any excess air in the tubing and balloon thus decompressing before placing in the Patient.
C. Place patient in supine position.
D. Insert TG using a sterile technique:
   i) Lubricate catheter using a water-based lubricant and proceed using standard hospital policy.
   ii) Insert catheter into the meatus until urine starts to flow.
   iii) Guide the catheter gently 5-8cm (Male) and 3-4cm (Female) beyond the point at which urine begins to flow.

   NOTE – The rationale for inserting further into the bladder ensures the retention balloon is beyond the neck of the bladder.

E. Inflate the retention balloon:
   i) Press firmly to attach syringe filled with 10cc of STERILE WATER to the RED port (retention balloon).
   ii) Inflate retention balloon with 10cc of STERILE WATER.
   iii) Disconnect syringe.
F. Retract the catheter until you feel resistance. The TG Catheter is now positioned properly in the bladder, critical to assure proper pressures.
G. Secure the catheter to the patient's thigh with a urinary catheter stabilization device.

3) Charging / Cable Connection

A. With patient in supine position inflate outer distal balloon:
   i) Pre-fill the 10cc syringe with 3cc's of STERILE WATER.
   ii) Press firmly to connect syringe filled with 3cc's of STERILE WATER to the WHITE port.
   iii) With Syringe upright, retract plunger enough to evacuate any excess air in the tubing.
   iv) Depress syringe again to inject exactly 3cc's of STERILE WATER into the WHITE port.

   NOTE – DO NOT PUSH ANY AIR INTO DISTAL BALLOON.

B. Remove RED protective cap covering the center pin on the catheter connector. Do not dispose of RED cap.
C. With patient in supine position connect the TG Cable to TG Catheter:
   i) Insert TG Cable into TG Catheter by lining up the two pins on TG Cable side with two openings on catheter.
   ii) Insert until firmly in place.
   iii) Twist locking mechanism clockwise until secure.

   NOTE – If TEMPERATURE reading is not visible on monitor after 30 seconds, unplug TG cable from TG Catheter, rotate cable connector 180 degrees and repeat above steps C i – iii.

D. Cable LED will be blinking WHITE.
E. Monitor is now displaying real time unfiltered IAP with patient in supine position.

Additional Cable Functionality:

LED Color	Cable Mode
Red	Error / Cable Malfunction
White	Unfiltered Real Time IAP
Green	Supine Filtered
Magenta (Purple)	Locked Supine Filtered
Cyan (Light Blue)	Elevated Filtered

F. To enter Supine Filter Mode which gives end-expiratory pressure:
   i) Press CAPTURE button on TG cable for three (3) seconds, cable LED will be blinking GREEN.
   ii) Allow up to 5 minutes to obtain an accurate pressure value.
   iii) If not changing position of the patient, continuous monitoring of IAP can stay at this setting.

   NOTE- DO NOT change patient position for 5 minutes as pressure will need this period to equilibrate and provide an accurate pressure.

4) Elevated Patient Positioning

A. Elevated Filtered Mode: TG will accurately monitor IAP in both supine position and with torso elevated (Elevated Filtered Mode):
   i) From Supine Filtered Mode (Cable LED blinking GREEN), press CAPTURE button on cable for three (3) seconds, then wait five (5) seconds to store Supine Filtered pressure reading. Cable LED will be Magenta (PURPLE).
B. Elevate patient to desired angle and wait for up to five (5) minutes or until pressure stabilizes BEFORE proceeding to step C.
C. Press CAPTURE button on cable for three (3) seconds to capture filtered IAP at desired elevation. Cable LED will be blinking BLUE.

   NOTE- This value is the IAP after the delta for the difference in pressure from supine to elevated position. To change patient position while Elevated (Elevated Filtered Mode cable LED blinking BLUE): This value is the IAP after the delta for the difference in pressure from supine to elevated position.

   NOTE- Side-to-side or rotational movement of the patient does not require re-setting pressure. If changing the elevation of the patient, proceed to step D.

D. Change patient elevation:
   i) First lower the patient to supine and press and hold mode and capture buttons simultaneously for ten (10) seconds until cable LED is blinking WHITE. TG is now measuring unfiltered real time IAP.
   ii) Follow above steps 4 A through C until cable LED is blinking BLUE at the new patient position.

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5) Recalibration

A. Recalibrate monitor per Hospital Policy but no longer than 48 hours. This procedure may also be followed if pressure readings are suspected to be inaccurate based on other clinical indicators:
   i) If Patient is elevated, return patient to Supine position.
   ii) Press and hold MODE and CAPTURE buttons simultaneously for ten (10) seconds until cable LED is blinking WHITE.

B. Disconnect cable from catheter:
   i) Twist cable locking ring counterclockwise until free.
   ii) Gently separate cable from catheter; be careful not to damage pins.
   iii) Cover center charging pin on the catheter connector with RED protective cap.

   NOTE – In the event the cable remains connected to the catheter when the patients' bedside monitor is zero'd, continuous IAP readings will read zero until the correct procedure is followed. When charting a patient's IAP, this zero value will indicate to the user a mistake has been made, and the correct procedure must be followed by zeroing with the cable disconnected from the catheter.

C. Disconnect cable from patient's bedside monitor.

D. Reconnect cable to the patient's bedside monitor. Monitor should read zero (0); If not, zero monitor to atmospheric pressure.

E. Cable LED will be blinking WHITE.

   NOTE – If cable LED is blinking RED, disconnect cable from patient's bedside monitor and repeat step D. If LED on cable is still blinking RED, DO NOT USE CABLE. Replace with a different TG cable.

F. Remove RED protective cap covering the center pin on the catheter connector. Do not dispose of RED cap.

G. With patient in supine position connect the TG Cable to TG:
   i) Insert TG Cable into TG Catheter by lining up the two pins on TG Cable side with two openings on catheter.
   ii) Insert until firmly in place.
   iii) Twist locking mechanism clockwise until secure.

   NOTE – If TEMPERATURE reading is not visible on monitor after 30 seconds, unplug TG cable from TG, rotate cable connector 180 degrees and repeat above steps G i - iii.

H. Cable LED will be blinking WHITE.

I. Monitor is now displaying real time unfiltered IAP with patient in supine position.

   NOTE - The original 3cc's of sterile water should remain in distal balloon of the catheter. No manipulation of volume is necessary. Abdominal pressure reading should return to approximately the last value seen prior to calibrating.

J. Follow steps 4 A-C for moving patient to an elevated patient position.

6) Troubleshooting

A. To reset cable at any time:
   i) If Patient is elevated, return patient to Supine position.
   ii) Press and hold MODE and CAPTURE buttons simultaneously for 10 seconds until cable LED is blinking WHITE.

   NOTE - If Cable LED is blinking RED, Cable is not properly communicating with patient's bedside monitor.

B. Disconnect cable from catheter:
   i) Twist cable locking ring counterclockwise until free.
   ii) Gently separate cable from catheter; be careful not to damage pins.
   iii) Cover center charging pin on the catheter connector with RED protective cap.

C. Disconnect cable from Patient's bedside monitor.

D. Reconnect cable to the Patient's bedside monitor.

E. Zero monitor to atmospheric pressure.

F. Cable LED should be blinking WHITE.

NOTE- If LED is still blinking RED, repeat steps 6B-F.
If LED remains RED, DO NOT USE CABLE. Replace with a different TG cable.

7) Cable Replacement

A. Disconnect cable from catheter:
   i) Twist cable locking ring counterclockwise until free.
   ii) Gently separate cable from catheter; be careful not to damage pins.
   iii) Cover center charging pin on the catheter connector with RED protective cap.

B. Disconnect cable from Patient's bedside monitor.

C. Connect replacement cable to monitor.

D. Zero monitor to atmospheric pressure.

E. Cable LED should be blinking WHITE.

8) Catheter Removal

A. Disconnect cable from catheter:
   i) Twist cable locking ring counterclockwise until free.
   ii) Gently separate cable from catheter; be careful not to damage pins.
   iii) Cover center charging pin on the catheter connector with RED protective cap.

B. Empty distal (pressure) balloon:
   i) Press firmly to connect an empty syringe to the WHITE port.
   ii) Withdraw all the STERILE WATER (3cc).
   iii) Disconnect syringe.

C. Empty proximal (retention) balloon:
   i) Press firmly to connect an empty syringe to the RED port.
   ii) Withdraw all the STERILE WATER (10cc).
   iii) Disconnect syringe.

D. Gently retract and remove the catheter.

E. Discard TG catheter according to Hospital policy.

9) Cable Maintenance and Storage

A. TG cable should be cleaned prior to connection to the TG catheter and when connecting from one Patient to another.

B. Use a sanitizing wipe or disposable lint-free cloth saturated with seventy percent (70%) isopropyl alcohol.

C. Wipe the cable from the proximal end up to the distal connector. Ensure the cable is moistened with alcohol and visibly air dried.

D. Do not submerge the cable.

E. Avoid getting fluid in sensor port and connectors at all times including during cable cleaning.

F. ENSURE PROTECTIVE CAP (TETHERED TO THE CABLE)

IS ON TRANSDUCER CABLE END AT ALL TIMES WHEN NOT IN USE.

TG catheter may be left in-situ for up to thirty (30) days. Regular patient monitoring should be undertaken to ensure there are no side effects and that the catheter is functioning correctly. Change TG according to Clinical Policies, not to exceed thirty (30) days in situ.

Possible Complications
In case the retention balloon or Outer Distal Balloon do not deflate, please refer to your local Clinical Policies to resolve the issue. Do not cut the balloon inflation valves.

If LED is RED, disconnect cable from patient's bedside monitor and follow steps 6 B-F. If LED on cable remains RED, DO NOT USE CABLE. Replace with a different TG cable.

WARNINGS:

Sterilization: Do Not Re-sterilize
TG catheter has been sterilized by E-Beam Radiation. The expiratory date can be found on the sterile pouch and the box. Damaged or open products may not be used.
TG is for single use only.
Cable is not MRI compatible and interference with imaging equipment may occur.
Disconnect reusable TG Cable from TG Catheter for MRI. The TG Cable is not MR safe so remove TG cable before MRI.
This product should never be connected to the monitor or connected to a cable during an MRI procedure. Failure to follow this guideline may result in serious injury to the patient.

Storage and Operating Environmental Conditions
TG should be stored in the original packaging in a cool dry place away from direct sunlight. TG should be used under ambient conditions for extended durations [ten to thirty degrees Celsius (15°C to 30°C), relative humidity of twenty-five to ninety percent (25% to 90%) and atmospheric pressure of sixty to one hundred two Kilopascal (60kPa to 102kPa)]. Storage should not exceed minus twenty to positive fifty degrees Celsius (-20°C to 50°C) and ten to ninety percent (10% to 90%) relative humidity.

Disposal
TG catheter and cable should be disposed of in line with your local Clinical Policies.

10) MRI Safety Information

Non- on-clinical testing has demonstrated the Sentinel TraumaGuard Intra-abdominal Pressure Sensing Catheter as MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions. Failure to follow these conditions may result in injury.

MRI Safety Information 

A patient with the Sentinel Medical Technologies TraumaGuard Catheter may be safely scanned under the following conditions when the catheter is disconnected from the monitoring system. Precautions should be taken to ensure that the metal pins at the hub of the catheter do not contact the patient. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Sentinel Medical Technologies TraumaGuard Catheter
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	24 T/m (2400 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, no restriction on local RF transmit-receive coils
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 1 hour of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of 18 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Reporting Serious Incidents:
If you experience a serious incident while using this device, or if you become aware of a serious incident involving this device, please report it to us immediately. A serious incident is any malfunction or deterioration in the performance of the device that has led to, or could lead to:

- The death of a patient, user, or other person.
- A serious deterioration in a person's state of health.
- An immediate public health threat.

You can report a serious incident by:

- **Email:** Send an email to info@sentinelmedtech.com
- **Phone:** Call us at +1-800-579-4910
- **Website:** Visit our website www.sentinelmedtech.com and navigate to the "Reporting Incidents" section.

Reporting timelines:

- For incidents posing an immediate public health threat, report within 2 days.
- For incidents leading to death or serious deterioration, report within 10 days.
- For all other serious incidents, report within 15 days.

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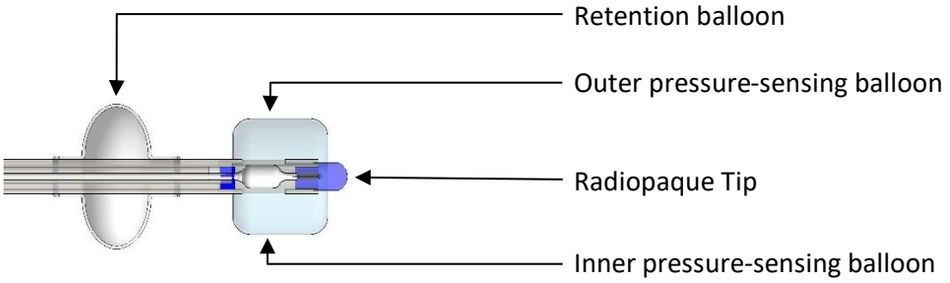
Figure 1. TraumaGuard Intra-abdominal Pressure-Sensing Catheter

Figure 2. TraumaGuard Balloons



Specifications:

TRAUMAGUARD CATHETER SPECIFICATIONS	
SKU: 000-0221	QTY / BX: 4
LENGTH: 50 cm	DISTAL BALLOON CC: 5.5 cc
SHAFT SIZE: 18 Fr	SINGLE USE / DISPOSABLE: Yes
RENTENTION BALLOON CC: 10 cc	LATEX FREE: Yes

*TraumaGuard works exclusively with Sentinel cables to measure pressure and temperature

TRAUMAGUARD CABLE SPECIFICATIONS	
SKU: 000-xxxx (Monitor Dependent)	QTY / BX: 1
OVERALL LENGTH: Approx. 0.914m (VARIES BY SKU)	USER INTERFACE: 2 Pushbuttons, 1 Multi-Color LED
CABLE DIAMETER: 3.9mm	SINGLE USE / DISPOSABLE: No
CABLE INSULATOR MATERIAL: TPU	ENCLOSURE MATERIAL: NYLON 12

Accessory Cable Pairing

The following table identifies correct pairing between the accessory and approved patient monitor:

Manufacturer	Monitor	Model	Compatible TG Cable
Philips	Intellivue MP Series	MP2, MP30, MP50, MP70, MP90	000-0250
	Intellivue MX Series	MX, MX400	000-0420
GE	Dash	4000	000-0260
GE	Carescape	B650, B850	000-0320
Nihon-Koden	Life Scope	MU631-RA	000-0280
Spacelabs	Ultraview SL	91370	000-0310
Spacelabs	Xprezzon	91393	000-0410
Mindray	Mindray	T1, N1, DPM6, DPM7	000-0330

TraumaGuard Intra-abdominal Pressure-Sensing System

REF	Catalogue Number	**TraumaGuard Intra-abdominal Pressure-Sensing Catheter** **CONTACT INFORMATION** **Sentinel Medical** 50 N Laura St, Ste. 2500 Jacksonville, Fl 32202 Phone: 1-800-579-4910 www.sentinelmedtech.com
LOT	Batch code	
	Do not Reuse – Single use	
	Do not re-sterilize	
STERILE R	Sterilized using irradiation	
	Use-by date	
	Consult instructions for use	
	Type BF Applied Part	
	Date of manufacture	
	Caution	
MR	MR Conditional	
IP21	Protected against solid foreign objects 12.5mm diameter and greater. Protected against vertically falling water drops	
	Humidity limitation	
	Temperature limit	
℞ Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	
	Do not use if package is damaged and consult *instructions for use*	
	Keep away from sunlight	
	Keep dry	
	Non-pyrogenic	
LATEX	Not made with natural rubber latex	
MD	*Medical device*	
UDI	Unique device identifier	
	Manufacturer	