The TEMED Gas Diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.
The TEMED Gas Diffuser is a single patient use disposable surgical device for effective insuffation of carbon dioxide (CO₂) into an open surgical wound. It aims to reduce the risk of air embolism by increasing the level of CO₂ in the local atmosphere. Air will enter the heart and great vessels during conventional open-heart surgery and can be difficult to evacuate with current de-airing techniques. Trapped air will be mobilized to the brain and other organs. Since CO₂ is 25 times more soluble than air in blood and tissue arterial CO₂ emboli will be fewer and also dissolve more quickly; decreasing the risk of organ injury if CO₂ is delivered to the surgical field. The density of CO₂ is 50% higher than air so it will naturally sink to the lowest point. Delivering CO₂ to the surgical field makes it possible to create, and maintain, an atmosphere of 100% CO₂ within the chest cavity.

**TEMED Diffuser**
Smooth, atraumatic tip allowing precise placement in the surgical field creating a consistent CO₂ atmosphere, a stable barrier against air embolism and bacteriological contamination.

**Standard open tube**
Uncontrolled jet of gas with the risk of turbulence, no stable barrier.
1/4" Gas Line Tubing

0.2 µm Microbial Gas Filter

Clear, Malleable Tubing

Hydrophobic, Diffusing Tip

1/4" Gas Line Tubing
The next step in diffusion

The **TEMED** Gas Diffuser has small pores which ensure that carbon dioxide is diffused over the majority of its surface therefore reducing turbulence.

Product with a soft sponge diffuser. The pore size means that the carbon dioxide appears to act just as water would do exiting a tap which has a diffuser inserted.

Standard quarter inch internal diameter tubing appears to deliver a plume of carbon dioxide in the same way as water would exit a tap without a diffuser inserted.

How have CO₂ delivery methods changed through time?
Why use the **TEMED** Gas Diffuser

Using the **TEMED** Gas Diffuser:

CO₂ saturation of a model chest cavity is achieved within 30 seconds of initiating the flow at only 2.5 lpm. This is a saving of 7.5 litres of CO₂ every minute, when compared to other marketed devices.

Helps to prevent air embolism during surgery
February 14, 2018

TEMED
Katie Evans
Quality Manager
Unit 3, Keynor Farm,
Keynor Lane, Sidlesham,
West Sussex PO20 7LL
United Kingdom

Re: K173545
   Trade/Device Name: TEMED Gas Diffuser
   Regulation Number: 21 CFR 884.1730
   Regulation Name: Laparoscopic Insufflator
   Regulatory Class: Class II
   Product Code: HIF
   Dated: October 30, 2017
   Received: November 16, 2017

Dear Katie Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part
Regulatory Information

TEMPED Gas Diffuser Clinical History

There have not been any reported incidents in the lifetime of the product, nor have there been any concerns raised by customers, competent authority or notified body (February 2018).

- TEMPED introduced its first CO₂ insufflation device to the European market in 2005
- The most recent model, the P2514, has been in production since 2010
- The TEMPED Gas Diffuser attained FDA 510 (K) approval for the USA market in February 2018
- The TEMPED Gas Diffuser attained TGA (Australia) approval in August 2011
- The P2514 has been used extensively throughout Europe, Australia and New Zealand.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole G. Ibrahim -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health
INSTRUCTIONS FOR USE
PRODUCT CODE: P2514  PRODUCT DESCRIPTION: TEMED GAS DIFFUSER

Please read all information carefully. Before using the TEMED Gas Diffuser the surgeon and other attending medical professionals must understand the user instructions.

CAUTION:
Federal (USA) law restricts device to sale by or on the order of a physician.

INTENDED USE
The TEMED Gas Diffuser is intended for use by cardiovascular surgeons in open heart surgery procedures for the insufflation of carbon dioxide gas into the thoracic cavity to reduce the risk of air embolism which can result in organ damage.

CONTRAINDICATIONS
The TEMED Gas Diffuser is not designed, sold, or intended for use except where indicated.

PREPARATION
Inspect the package before opening. Ensure that the product is in date. If there is any damage to the package or product do not use the product. Report the damage to the supplier and keep both the packaging and the product so that the cause of the damage can be investigated.

Ensure that you have a supply of medical grade carbon dioxide sufficient to deliver up to 10l/min for the duration of the operation.

The flow meter shall contain or be connected to a pressure regulator. The service pressure for CO$_2$ gas is set at 3.5 – 4.5 bar (50 – 60 psi or 350-450 kpa).

Place the tip (the black and white section) of the product at the caudal end of the wound. Bend the clear tubing so that the tip is placed approximately 2 inches (5cm) below the skin surface.

Immobilize the tubing.

Connect the open part of the green tubing to the flow meter.

DIRECTIONS FOR USE
Start a gas flow of CO$_2$ of up to 10 liters /minute at least 1 minute before opening of the heart, lung veins and great vessels.

Continue the flow of gas until the closure of the heart, lung veins and great vessels is complete.

When using a suction device inside the wound cavity, avoid using a suction rate that exceeds the CO$_2$ gas flow rate. If the TEMED gas flow rate is exceeded by the suction rate the cavity may be depleted of CO$_2$ and filled with air.

STORAGE
The storage temperature should not be below 1 degree Celsius or above 40 degrees Celsius. The product should be stored away from moisture, direct heat and sunlight.

TEMED Gas Diffuser Components
<table>
<thead>
<tr>
<th>Hose</th>
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</thead>
<tbody>
<tr>
<td>Filter Housing</td>
</tr>
<tr>
<td>Filter</td>
</tr>
<tr>
<td>Diffusing Tip</td>
</tr>
<tr>
<td>Adhesive</td>
</tr>
<tr>
<td>Connector between ¼ inch tubing and malleable section</td>
</tr>
<tr>
<td>Malleable section</td>
</tr>
<tr>
<td>Gas Flow Rate</td>
</tr>
<tr>
<td>Storage Temperature (°C)</td>
</tr>
</tbody>
</table>

TEMED Gas Diffuser materials
| PVC |
| Polypropylene |
| Glass fiber |
| High Density Polyethylene |
| Cyclohexanone |
| PVC |
| CAS-Nr. 9002-86-2 |
| PVC and a stainless steel wire in the flexible section |
| Up to 10 liters per minute |
| Not lower than 1 degree Celsius and not higher than 40 degrees celsius |

PRECAUTIONS
- The TEMED Gas Diffuser is a single use device and should not be reused. Any unused, open product should be discarded.
- Do not exert excessive traction force on the device.
Instructions for use: **TEMED** Gas Diffuser P2514

**DISPOSAL**
- The device is designed for single use only. Do not re-sterilize or reuse.
- Ensure that the device has not been severed by any cut or excessive traction force.
- After use the TEMED Gas Diffuser should be disposed of according to hospital procedure for contaminated material.
- Do not reuse due to the risk of infection.

**WARRANTY AND LIMITATION OF LIABILITY**
A. The manufacturer warrants that the TEMED Gas Diffuser has been manufactured in accordance with its specifications and in compliance with Good Manufacturing Practices as dictated by ISO 13485:2012, and other applicable industry standards and regulatory requirements.
B. The manufacturer will replace any TEMED Gas Diffuser with manufacturing defects if the defect is reported within the lifetime of the product and that product is returned to the manufacturer for inspection.
C. The above-mentioned warranty is in lieu of, and to the exclusion of any other warranty, whether written or oral, expressed or implied, statutory or otherwise and there are no warranties or merchantability or other warranties which extend beyond those described above. The remedy set out above for manufacturing defects is the sole remedy available to any person due to defects in the TEMED Gas Diffuser and the manufacturer shall not be liable for any consequential or incidental loss, damage, injury or expense arising directly or indirectly from the use of the TEMED Gas Diffuser, whether as a result of any defect therein or otherwise.
D. The manufacturer or distributor shall not be liable for any misuse, improper handling, non-compliance with warnings, precautions, instructions, damage arising from events after the manufacturer release of the TEMED Gas Diffuser, failure or omission to inspect the TEMED Gas Diffuser before use to ensure that the TEMED Gas Diffuser is in proper condition, or any warranty given by independent distributors or dealers.

**MANUFACTURER:**
HMT Medizintechnik GmbH, Frauenstr 30, 82216 Maisach, Germany    Telephone: +49 (0)8141 4003 0

**MANUFACTURED FOR:**
TEMED, Unit 3, Keynor Farm, Keynor Lane, Sidlesham, PO20 7LL, UK. Telephone 0044 (0) 1243 572255
Email sales@temed.net, webpage www.temed.net

**EXPLANATION OF SYMBOLS ON PACKAGING LABELS**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Explanation</th>
<th>Symbol</th>
<th>Explanation</th>
<th>Symbol</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Manufacturer]</td>
<td>Manufacturer</td>
<td>![Do not re-sterilize]</td>
<td>Do not re-sterilize.</td>
<td>![Pyrogen free]</td>
<td>Pyrogen free.</td>
</tr>
<tr>
<td>![CE mark and notified body number]</td>
<td>0481 CE mark and notified body number</td>
<td>![Do not use if package is opened or damaged]</td>
<td>Do not use if package is opened or damaged.</td>
<td>![LOT]</td>
<td>The lot number of the product, used for traceability purposes.</td>
</tr>
<tr>
<td>![Do not re-use. Single use only]</td>
<td>Do not re-use. Single use only</td>
<td>![Contains phthalates DEHP]</td>
<td>Contains phthalates DEHP.</td>
<td>![Use by]</td>
<td>Use by.</td>
</tr>
<tr>
<td>![Do not use if package is opened or damaged]</td>
<td>Do not use if package is opened or damaged.</td>
<td>![Read the instructions for use]</td>
<td>Read the instructions for use.</td>
<td>![REF]</td>
<td>The product code number, used to identity the product.</td>
</tr>
<tr>
<td>![Date of manufacture]</td>
<td>Date of manufacture.</td>
<td>![STERILE CO]</td>
<td>States the method of sterilisation is by Ethylene Oxide.</td>
<td>![Do not use if package is opened or damaged]</td>
<td>Do not use if package is opened or damaged.</td>
</tr>
<tr>
<td>![Temperature limitations]</td>
<td>Temperature limitations. To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.</td>
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</table>
Physical features of the TEMED Gas Diffuser

0.2 µm MICROBIAL GAS FILTER
- The 0.2 micron microbial gas filter is an important element of the TEMED Gas Diffuser.
  - The filter is used to sterilise the carbon dioxide passing from the gas bottle or wall gas source to the diffusing tip.
  - Larger filter sizes such as 0.4 micron can let the Brevundimonas Dimiuta bacteria through.

CLEAR MALLEABLE DUAL LUMEN TUBING WITH ANNEALED STEEL REINFORCEMENT
- The clear malleable dual lumen tubing is the section which is visualised in the surgical field. The tubing is clear for a number of reasons:
  - The surgical field can be a cluttered environment. By utilising clear tubing to deliver the gas we are ensuring that there is minimal visual obstruction caused by using the TEMED Gas Diffuser.
  - The clear tubing allows the surgeon to see the pathway that the Carbon Dioxide gas is travelling through before it exits the Gas Diffuser. The surgeon will therefore be able to identify any potential issues which might arise due to the obstruction of the gas delivery line.
  - The clear tubed section is reinforced with annealed steel. The surgeon can therefore bend the malleable section into the shape that is required for efficient placement.

GREEN GAS LINE TUBING
- The gas line tubing which delivers the CO₂ to the surgical field is tinted green and transparent:
  - The green colour is used to identify that it is a gas line.
  - By being transparent it allows the Surgeon, Anaesthetist, Perfusionist or Nurse to identify if there is condensation within the delivery line which may impede the delivery of gas to the surgical field.

- The ¼ inch internal diameter of the gas line allows a push-fit connection to the regulator.
HYDROPHOBIC DIFFUSING TIP

- The distal section of the TEMED Gas Diffuser is manufactured from a hydrophobic material which is firm to the touch.
  - Being hydrophobic, the tip is able to diffuse gas over the majority of its surface despite any accidental submersion in fluid by the user.
  - The design enables the surgeons to have confidence that the product will not wet out.

- The diffusing tip is manufactured using the two contrasting colours of black and white.
  - The two colours easily identify the distal section of the TEMED Gas Diffuser in the potentially cluttered environment of the surgical field.

DOUBLE BAGGED

- The TEMED Gas Diffuser is double bagged.
  - This method of packing means that the product can easily be presented to the surgical field.
  - The outer bag can be opened with an aseptic technique and the inner bag containing the product can be placed onto a sterile trolley if required.
  - The double bagging of the product also ensures that the label is tamper proof as the label is fixed to the inner bag and viewed through the transparent section of the outer bag.
Why use Carbon Dioxide?

Carbon dioxide field flooding reduces neurologic impairment after open heart surgery.
Ann Thorac Surg. 2008 Feb;85(2):543-7:
“Shorter P300 peak latencies after surgery indicate less brain damage in patients who underwent heart valve operations with CO2 flooding of the thoracic cavity.”

Wound ventilation with carbon dioxide: a simple method to prevent direct airborne contamination during cardiac surgery?
Persson M, van der Linden J., J Hosp Infect. 2004 Feb;56(2):131-6:
“Intraoperative wound ventilation with CO2 using a gas-diffuser may not only prevent air embolism, but may also significantly reduce the risk of airborne contamination and postoperative wound infection in cardiac surgery.”

Effect of CO2 insufflation on the number and behavior of air microemboli in open-heart surgery: a randomized clinical trial.
“Insufflation of CO2 into the thoracic wound markedly decreases the incidence of microemboli.”

Carbon dioxide in the prevention of air embolism during open-heart surgery
W. SHANG NG AND MICHAEL ROSEN. Thorax (1968), 23, 194.
“During any open-heart operation there is a danger of embolism from air trapped in the heart. One of the ways of reducing this is to displace the air in the wound by carbon dioxide (Myerly, Throckmorton, and Gustafson, 1957; Nichols, Morse, and Hirose, 1958; Ogawa, Kai, Seno, Taguchi, Kurihara, Fujimara, Kato, Hirano, and Adachi, 1962; Eguchi, Sakurai, and Yamaguchi, 1963; Effler, Groves, and Gulati, 1964; Burbank, Ferguson, and Burford, 1965). The solubility of carbon dioxide in blood is greater than that of air, in which nitrogen is the important relatively insoluble component (Table I). The serious effects that follow air trapped in the arterial system should be diminished by replacing this air with an equal quantity of carbon dioxide.”

Skidmore KL1, Jones C, DeWet C.
Flooding the surgical field with carbon dioxide during open heart surgery improves segmental wall motion.
“We recommend administration of carbon dioxide”