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BTG | Interventional Pulmonology PneumRx

30 April 2018

Dear PneumRx RePneu™ Coil System Physician Users,

This Service Bulletin is to notify you of updates to the Instructions for Use (LBL0139, updated from Rev. I to Rev. J, dated 2017/12) for the PneumRx RePneu™ Lung Volume Reduction Coil System.

The Instructions for Use document has been updated as part of PneumRx's post-market surveillance program, and in consideration of the recently completed usability testing and Instructions for Use provided in PneumRx's Premarket Approval (PMA) application to FDA.

The patient safety-related updates are summarized below. A complete list of all changes is presented in **Appendix 1**.

Changes to Section 3.0 – Contraindications

- Revised contraindications regarding:
  - Giant bullae by providing a more specific description of the contraindicated condition.
  - Pulmonary hypertension by adding new note (Note: For further guidance, see Section 4.3.5 – Pulmonary Hypertension).
  - Immunosuppressive drugs for clarification of language.

- Deleted contraindication regarding:
  - Vessel size and converted it to a new warning in **Section 4.3.5 – Pulmonary Hypertension** with specific examples for the user to confirm the absence of hypertension. The specific contraindication regarding pulmonary hypertension (8th bullet point) is still included in **Section 3.0 – Contraindications**.

Imagine where we can go.

Changes to Section 4.0 – Warnings

Section 4.2 – Coil Removal Warnings

- Created new section: **Section 4.2 – Coil Removal Warnings**
- Repeated Coil removal warnings from **Section 13.0 – Bronchoscopic Coil Removal Following Implantation** to enhance safe use of the product.
- Added new note regarding the minimum inner diameter (2.0mm) of the therapeutic bronchoscope used for Coil removal subsequent to the implantation procedure. This informs users that a smaller inner diameter bronchoscope is required for Coil removal (same change made in section 8.1).

Section 4.3 – Warnings Regarding Patient Pre-Existing Conditions

- Revised title from “General Warnings” to “Warnings Regarding Patient Pre-existing Conditions”.
- Created new:
  - Subsections (shown below) to draw attention to warnings regarding patient pre-existing conditions:
    - 4.3.1 – Hempotysis and Anticoagulation
    - 4.3.2 – Bronchiectasis and Atelectasis
    - 4.3.3 – Cancerous Lung Nodules/Other Lung Conditions
    - 4.3.4 – Asthma-predominance
    - 4.3.5 – Pulmonary Hypertension
  - Warning in **subsection 4.3.4 - Asthma-predominance** for clarification to support appropriate patient selection, including patients excluded from randomized clinical trials.
  - Warning in **subsection 4.3.5 – Pulmonary Hypertension** (converted from previous contraindication) to provide specific examples of vessel size imaging findings that may be observed and should be followed-up to determine if a contraindicated condition is present.
- Modified warning statement regarding bronchiectasis and atelectasis to present the risk of Coil implantation in patients with these conditions before advising not to implant Coils in the affected lobes.
- Added new note (Note: For additional patient selection considerations, see **Section 6.0 – Individualization of Treatment**).

Section 4.4 – RePneu Coil and Delivery System Warnings

- Changed two warning statements to caution statements because they relate to procedural precautions (not patient safety information):
  - Do not advance the Catheter without Guidewire support. When advancing the Catheter, always lead with the Guidewire.
  - Do not advance the RePneu System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black proximal marker band on the Forceps enters the Cartridge.

Changes to Section 5.0 – Precautions

Section 5.1 – General Precautions

- Revised second bullet point to specify that the RePneu™ Endobronbchial Coil Procedure is to be performed in two separate sessions.

Section 5.2 – Procedural Precautions

- Revised existing single precaution regarding Coil placement into two separate precautions:
  - Coils should be placed so that they are not in contact with adjacent Coils in order to avoid metal-on-metal friction.
  - Avoid placing two Coils in the same airway.

Changes to Section 6.0 – Individualization of Treatment

- Removed "Low FEV_1" because it is not a specific descriptor that is helpful to the reader.

Section 6.1 – Use in Special Populations

- Added, "Patients with a change in FEV_1 >20% post-bronchodilator (or, for patients with pre-bronchodilator FEV_1 below 1L, a change of >200mL) unless physician confirmed by other means that the patient does not have asthma" to include all required information regarding populations not studied in one place.

Changes to Section 7.0 – Potential Adverse Events

- Added "Lung Abscess" and "Pneumonitis" in response to complaints received.
- Revised Note regarding CAO to provide additional information regarding diagnosing CAO based on imaging and the necessity for prompt intervention.

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Changes to Section 8.0 – Clinician Use Information

Section 8.2 – Peri-procedural Care

- Reworded follow-up statement to indicate that a fluoroscopic image/X-ray should be performed post-procedure.

Changes to Section 11.0 – Directions for Use

- Added 7 precautions (from **Section 5.2 – Procedural Precautions**) and one warning (from **Section 4.4 – RePneu Coil and Delivery System Warnings**) to enhance safe use of the product.
- Revised Step 29(b) to provide specific instructions regarding Coil placement and the necessity for Coil repositioning if the proximal end of the Coil is pressing into the tissue.

Changes to Section 13.0 – Bronchoscopic Coil Removal Following Implantation

- Revised 1st warning to add "(e.g., persistent pleuritic pain)" as a specific example of a reason for Coil removal to add clarity for the reader.
- Bolded the words "**after 2 or more months**" in the warning statement regarding Coil removal.

As the list above is not comprehensive, please take some time to read over the new Instructions for Use. The revised Instructions for Use are available for download in 14 different languages at http://pneumrx.com/en/corporate/instructions-for-use/.

If you should have questions on any of these updates, please reach out to your respective PneumRx sales representative [*Insert Sales Representative Name*] or Clinical Field Specialist, or e-mail PneumRx at ServiceBulletin@btgplc.com.

PneumRx would like to thank you for your ongoing support and feedback as it relates to the PneumRx RePneu™ Coil System.

Best Regards,

David Hahn, MD, Vice President of Medical Affairs and Education

Susan Stolfi, Director of Professional Education

Appendix 1

Changes to Cover Page

Description of Change	Reason for Update
Deleted Fax number and added email address	FAX is rarely used and Email is a more current method of communication.

Changes to Section 1.0 – Device Description

Description of Change	Reason for Update
In first paragraph, change “REPNEU Coil” to “REPNEU Coils”.	To reflect plural noun used in subsequent text.

Changes to Section 3.0 – Contraindications

Description of Change	Reason for Update
Revise 6th bullet point regarding giant bullae: **From:** Patients with giant bullae >1/3 of the lung volume **To:** Patients with severe bullous disease (defined by bulla >1/3 of lung volume, or single bullous defect >8cm), or significant paraseptal emphysema [defined by numerous large (>1cm) paraseptal defects in the target lobe comprising >5% of total lung volume].	Improve clarity by providing a more specific description of contraindicated condition including the meaning of ‘significant paraseptal emphysema’.
Revise 8th bullet point regarding pulmonary hypertension to add “Note: - For further guidance, see Section 4.3.5 – Pulmonary Hypertension”.	To refer the reader to the section containing additional information regarding the need for measurement for pulmonary hypertension.
Delete 9th bullet point regarding vessel size and added new warning. (Section 4.3.5 – Pulmonary hypertension).	This language was inappropriate as a contraindication. Visual estimation is not adequate to diagnose pulmonary hypertension. Instead, visual estimation should be a warning confirmed by means of a physiologic measurement. The language was converted to a new warning in Section 4.3.5 with more examples of potential visual findings, and which directs the user to confirm the absence of hypertension.

Description of Change	Reason for Update
	The specific contraindication regarding pulmonary hypertension (8th bullet point) is still included in Section 3.0 – Contraindications.
Revise 10th bullet point regarding immunosuppressive drugs: **From:** Patients taking immunosuppressive drugs for the treatment of cancer, rheumatoid arthritis, autoimmune disease, or prevention of tissue or organ rejection. **To:** Patients taking immunosuppressive drugs other than steroids (e.g., for the treatment of cancer, rheumatoid arthritis, autoimmune disease, or prevention of tissue or organ rejection).	Clarification of language. Low doses of steroids can have some immunosuppressive effect but are acceptable. High doses of drugs specifically taken to suppress the immune system (such as those taken for cancer, autoimmune disease, etc.) are not acceptable.
Deleted space between "20" and "mg" in 11th contraindication.	Typographical error correction.

Changes to Section 4.1 – Clinician Use Warnings

Description of Change	Reason for Update
Add "by a PneumRx representative" to training statement.	Clarification of language.

Changes to Section 4.2 – Coil Removal Warnings

Description of Change	Reason for Update
Created new "Section 4.2 – Coil Removal Warnings" to repeat Coil removal warnings in Section 13.0 – Bronchoscopic Coil Removal Following Implantation.	Repetition of information already existing in Section 13.0, but brought forward to warnings section.
Added new Note: ***Note:*** Bronchoscopic Coil removal subsequent to the implantation procedure must be performed using a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length.	Note to describe bronchoscope necessary, including inner diameter, for post-procedure Coil removal vs. repositioning of Coil during implantation procedure.

Changes to Section 4.3 – Warnings Regarding Patient Pre-Existing Conditions

Description of Change	Reason for Update
Revised Section title from “General Warnings” to “Warnings Regarding Patient Pre-existing Conditions”.	Improves usability for reader to find required information.
Added the following subsections to draw attention to warnings regarding specific patient pre-existing conditions: 4.3.1 – Hemoptysis and Anticoagulation 4.3.2 – Bronchiectasis and Atelectasis 4.3.3 – Cancerous Lung Nodules/Other Lung Conditions 4.3.4 – Asthma-predominance 4.3.5 – Pulmonary Hypertension	Improves usability for reader to find required information.
4.3.2 – Bronchiectasis and Atelectasis Modified warning statement so the last sentence comes first. **From:** Do not implant REPNEU Coils in any area of the lung exhibiting bronchiectasis or significant atelectasis. To decrease the risk of serious pulmonary bleeding events, Coil implantation should be performed in patients with bronchiectasis only after careful consideration, avoiding any suspect areas of the lung. **To:** To decrease the risk of serious pulmonary bleeding events, Coil implantation should be performed in patients with bronchiectasis only after careful consideration, avoiding any suspect areas of the lung. Do not implant REPNEU Coils in any area of the lung exhibiting bronchiectasis or significant atelectasis.	To present the risk of bronchiectasis and atelectasis before advice not to implant Coils in the affected lobe.
4.3.3 – Cancerous Lung Nodules/Other Lung Conditions Revise remaining bullet point to delete “or” and replace with “in consideration of”.	Clarification to emphasize the need for user to consider risk and benefits for the particular patient prior to the procedure.
4.3.4 – Asthma-predominance New Section with one bullet point:	Clarification to support appropriate patient selection, including patients excluded from randomized clinical trials. Aligns with the indications for use and RENEW study inclusion

Description of Change	Reason for Update
• In patients with asthma COPD overlap, asthma predominant disease should be ruled out by the treating physician. Patients with significant bronchodilator reversibility of FEV_1 (FEV_1 >20% post-bronchodilator) have not been clinically evaluated. See **Section 6.1 – Use in Special Populations** for a list of other patient populations that have not been evaluated in clinical studies.	criteria to eliminate patients who have asthma rather than emphysema.
4.3.5 – Pulmonary Hypertension New Section with one bullet point: • Patients with imaging findings indicative of severe pulmonary hypertension (e.g., a segmental artery-to-bronchus ratio greater than 1:1 in three of four pulmonary lobes) should undergo further testing to rule out severe pulmonary hypertension, which is a contraindicated condition.	New warning converted from 9th Contraindication (regarding vessel size) which has been deleted. New wording provides specific examples of vessel size imaging findings that may be observed and should be followed up to determine if a contraindicated condition is present.
4.3 – Warnings Regarding Patient Pre-Existing Conditions Added new Note directing reader to Section 6.0 - Individualization of Treatment, for additional patient selection considerations: ***Note*:** For additional patient selection considerations, see **Section 6.0 – Individualization of Treatment**	Improves usability for reader to find required information.
4.4 – REPNEU Coil and Delivery System Warnings Changed the 1st warning to a caution statement: • Do not advance the Catheter without Guidewire support. When advancing the Catheter, always lead with the Guidewire. Moved the statement to Section 5.2 – Procedural Precautions (5th bullet point) and added to Section 11 – Directions for Use, Step 6.	Changed the warning statement to a caution statement because it relates to procedural cautions (not patient safety information).
4.4 – REPNEU Coil and Delivery System Warnings Changed the 2st warning to a caution statement: • Do not advance the REPNEU System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black	Changed the warning statement to a caution statement because it relates to procedural cautions (not patient safety information).

Description of Change	Reason for Update
proximal marker band on the forceps enters the Cartridge. Moved the statement to Section 5.2 – Procedural Precautions (15th bullet point) and added to Section 11 – Directions for Use, Step 24.	
Moved the 4th and 5th warnings regarding Coil removal to Section 4.2 – Coil Removal Warnings (and split one warning into two, resulting in three separate warnings). • Bronchoscopic Coil removal **must be medically indicated** (e.g., persistent pleuritic pain). The potential benefit of Coil removal must be weighed against the potential harm including the known risks of bronchoscopy. • Removing Coils bronchoscopically may become increasingly difficult **after 2 or more months** following implantation, depending on the amount of tissue regrowth present. If bronchoscopic removal is not possible, surgical removal using a thoracoscopic approach can be considered. See **Section 13.0 - Bronchoscopic Coil Removal Following Implantation** for procedural details. • If Coil removal is required, do not attempt to cut through, bend or break the Coil in any manner. Mishandling of the Coil in this manner can result in corrosion of the device and creation of sharp surfaces that can lead to injury, illness or death of the patient.	Improves usability for reader to find required information.

Changes to Section 5.1 – General Precautions

Description of Change	Reason for Update
Revised second bullet point: **From:** The REPNEU Endobronchial Coil procedure is a bilateral treatment that should be performed in separate sessions.	To clarify that there are two procedures.

Description of Change	Reason for Update
To: The REPNEU Endobronchial Coil procedure is a bilateral treatment that should be performed in two separate sessions.	

Changes to Section 5.2 – Procedural Precautions

Description of Change	Reason for Update
Reordered precautions to match order as listed in Section 11 – Directions for Use and Section 13 – Bronchoscopic Coil Removal Following Implantation.	Improves usability for reader to find required information.
Modified precaution to change “trapped” to “pinched” to match caution statement in Section 11 – Directions for Use: **From:** Forcing the Guidewire past a sudden curve in a distal airway could cause tissue to become trapped within the curved portion of the guidewire. **To:** Forcing the Guidewire past a sudden curve in a distal airway could cause tissue to become pinched within the curved portion of the guidewire.	Correction to ensure consistency.
Changed existing precaution: **From:** • Coils should be placed to avoid touching or overlapping. Use extreme caution to avoid placing two Coils in the same airway. **To (two precautions):** • Coils should be placed so that they are not in contact with adjacent Coils in order to avoid metal-on-metal friction. • Avoid placing two Coils in the same airway.	Clarification providing specific examples and reason for avoidance of touching and overlapping.
Deleted one precaution (not listed in Section 11 – Directions for Use): • When Delivery system components are beyond the visual range of the bronchoscope, they should be manipulated only under fluoroscopy.	Deleted caution statement due to redundancy with the following caution statement: • Do not advance the REPNEU System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black proximal marker

Description of Change	Reason for Update
	band on the Forceps enters the Cartridge.

Changes to 6.0 – Individualization of Treatment

Description of Change	Reason for Update
In second paragraph, changed “RENEW study” to “RENEW Pivotal Trial”.	To clarify status of the RENEW study.
Removed the following: - Low FEV_1	“Low FEV_1” is not a specific descriptor that is helpful to the reader. Subjects with FEV_1 % predicted values ranging from 12.9% to 43.6% were studied in the RENEW study. This information has been modified and also moved to Section 6.1 – Use in Special Populations.

Changes to Section 6.1 – Use in Special Populations

Description of Change	Reason for Update
Added the following: • Patients with a change in FEV_1 >20% post-bronchodilator (or, for patients with pre-bronchodilator FEV_1 below 1L, a change of >200mL) unless physician confirmed by other means that the patient does not have asthma.	Improves usability by including all required information regarding populations not studied in one place, Section 6.1 – Use in Special Populations.

Changes to Section 7.0 – Potential Adverse Events

Description of Change	Reason for Update
Revised to add the following: • Lung Abscess	Added “Lung Abscess” as a result of complaint received for “lung abscess” (CAL-PC-17-0005).
Revised to add the following: • Pneumonitis	Added “Pneumonitis” as a result of complaint received for “pneumonitis” (48-09-502)

Description of Change	Reason for Update
Revised Note: **From: "***Note:* Additional interventional procedures may be necessary if patients experience some of these potential adverse event(s) following REPNEU Coil treatment. * There have been reports of non-infectious localized tissue reaction, also termed Coil Associated Opacity (CAO), in the area of implanted REPNEU Coils. This is believed to be an inflammatory reaction that presents with pneumonia-like symptoms, including chest or pleuritic pain/discomfort, increased dyspnea, fatigue, and/or haze or infiltrates on chest X-ray, and may be difficult to distinguish from pneumonia. Therefore, patients should be instructed at discharge to contact their implanting physician if they experience symptoms that may be indicative of pneumonia or CAO. **To: "***Note:* Additional interventional procedures may be necessary if patients experience some of these potential adverse event(s) following REPNEU Coil treatment. * A recognized, non-infectious localized tissue reaction, also termed Coil Associated Opacity (CAO), may occur in the area of implanted REPNEU Coils and is typically diagnosed on imaging (chest X-ray or CT scan). This is believed to be an inflammatory response that presents with pneumonia-like symptoms, including chest or pleuritic pain/discomfort, increased dyspnea, fatigue, and/or haze or infiltrates on chest X-ray, and may be difficult to distinguish from pneumonia. While some degree of CAO has been observed in clinical trials up to 2 months following the Coil procedure, many of these events are asymptomatic or symptomatically mild, resolve with limited intervention, and do not develop into serious adverse events (SAEs). However, CAO can become severe and require prompt and specific intervention. Thus, patients are advised to contact their treating physician immediately for follow-up if they experience pneumonia-like symptoms."	Additional detail inserted to reflect PneumRx's current understanding of CAO and appropriate treatment.

Changes to Section 8.1 – Materials Required

Description of Change	Reason for Update
Added new Note: *Note*: Bronchoscopic Coil removal subsequent to the implantation procedure must be performed using a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length.	Note to describe bronchoscope necessary, including inner diameter, for post-procedure Coil removal vs. repositioning of Coil during implantation procedure.

Changes to Section 8.2 – Peri-procedural Care

Description of Change	Reason for Update
Reworded follow-up statement: **From:** "A chest X-ray should be done post-procedure to verify Coil placement and to ensure no pneumothorax is present. A second chest X-ray should be done at least 4 hours following the first chest X-ray." **To:** "A chest fluoroscopic image/X-ray should be taken post-procedure to verify Coil placement and to ensure no pneumothorax is present. A second chest X-ray should be done before discharge, a minimum of 4 hours following the first chest X-ray."	Clarification to specify that a fluoroscopic image should be taken post-procedure and a second chest X-ray should be performed prior to discharge (not solely within a specific time frame).
Changed "…the treating physician" to "…their treating physician" in 5th paragraph.	To improve grammar.

Changes to Section 9.1 – Patient Implant Card and Patient Brochure

Description of Change	Reason for Update
Changed email address: **From:** CS@btgplc.com **To:** pneumrx@btgplc.com	Previous email address had inappropriate routing.

Changes to Section 11.0 – Directions for Use

Description of Change	Reason for Update
Added 7 precautions (from Section 5.2 – Procedural Precautions) and one warning (from Section 4.4 – RePneu Coil and Delivery System Warnings):	Repetition of precautions included in Section 5.2 – Procedural Precautions and one warning from

Description of Change	Reason for Update
⚠ ***Caution:*** **Always use a bronchoscope for the procedure. The REPNEU System is intended to be used with a therapeutic bronchoscope with a 2.8mm inner diameter working channel and a 65cm maximum working length. Use of the REPNEU System with bronchoscopes not meeting these criteria may result in equipment or device damage.** ⚠ ***Caution:*** **Do not use a kinked Delivery System or Coil.** ⚠ ***Caution:*** **Coils should be placed so that they are not in contact with adjacent Coils in order to avoid metal on metal friction.** ⚠ ***Caution*****: Avoid placing two Coils in the same airway.** ⚠ ***Caution*****: Do not advance the Catheter without Guidewire support. When advancing the Catheter, always lead with the Guidewire.** ⚠ ***Caution*****: Do not advance the REPNEU System components beyond the visual range of the bronchoscope unless under fluoroscopic visualization. Turn fluoroscopy on when the black proximal marker band on the Forceps enters the Cartridge.** ⚠ ***Caution*****: Do not attempt to deliver Coils without using fluoroscopy.** **WARNING: To avoid puncturing the pleura or causing airway trauma, never advance the Guidewire, Catheter, or any other REPNEU System component against resistance. If**	Section 4.4 – RePneu Coil and Delivery System Warnings. These caution statements and warning were missing from Section 11.0 – Directions for Use.

Description of Change	Reason for Update
resistance is met, determine the cause and take remedial action before again attempting to advance the REPNEU System component.	
Reworded statement in Step #4(b) as follows: **From:** "Start deploying Coils in the segment which presents the most difficult access first and progress to less difficult segments". **To:** "Deployment of Coils should start in the segment which presents the most difficult access first, and then progress to less difficult segments".	Reworded to reflect that user is not yet deploying Coils at this point of the procedure description.
Reworded statement in Step #6 as follows: **From:** "Align the tip of the Guidewire and the Catheter." **To:** "Advance the tip of the Guidewire so that approximately 1mm protrudes out from the end of the Catheter".	Clarification. Removed the word "align" and provide instruction to ensure that the guidewire protrudes slightly out from the end of the Catheter.
Modified Figure 3 to change figure title to "Advance Guidewire Slightly Beyond Catheter Tip" and include a call-out to identify "Guidewire Tip" added "(see Figure 3)" to the end of Step #6. Renumbered subsequent Figures accordingly.	To improve clarity of Figure title and provide image with call-out to draw attention to Guidewire tip.
Added new Figure 4 (Insert Catheter and Guidewire Together) immediately after Step #7 and added "(see Figure 4)" to the end of Step #7. Renumbered subsequent Figures accordingly.	To improve usability by providing a new image showing insertion of the Catheter and Guidewire together into the bronchoscope.
Repositioned tip of arrow in Figure 5 to point more directly at Catheter.	To ensure that arrow is pointing at Catheter and not at Bronchoscope.
Moved Step 13 directly below Step 12 and broke Step 13 into two separate sentences as follows: **From:** "Remove the Guidewire from the Catheter while maintaining the Catheter position and turn fluoroscopy off."	Improves usability for reader to find required information by making Step 13 more visible (since it is no longer hidden under Table 1). Modified sentence to clarify that fluoroscopy should be turned off after removing the Guidewire from the Catheter.

Description of Change	Reason for Update
To: "Remove the Guidewire from the Catheter while maintaining the Catheter position. Turn fluoroscopy off after the Guidewire is removed from the Catheter."	
Added new Figure 9 (Opening Forceps) immediately after Step #17 and added "(see Figure 9)" to the end of Step #17.Renumbered subsequent Figures accordingly.	To improve usability by providing a new image showing how the Forceps are opened.
Added new Figure 10 (Grasp Coil by Closing Forceps Jaws) immediately after Step #18 and added "(see Figure 10)" to the end of Step #18. Renumbered subsequent Figures accordingly.	To improve usability by providing a new image showing how to grasp the Coil using the Forceps jaws.
Step #19 - Removed parenthesis from the sentence "Press the blue locking tab to the handle until an audible clicking sound is heard to prevent releasing the Coil".	Clarified sentence for reader.
Added new Figure 11 (Closing Forceps) and Figure 12 (Locking Forceps) immediately after Step #19 and added "(see Figure 11 and Figure 12)" to Step #19. Renumbered subsequent Figures accordingly.	To improve usability by providing new images showing how to close and lock the Forceps jaws.
Changed title of Figure 13: **From:** "Pulling Coil into the Cartridge" **To:** "Seat Cartridge into Shell"	To accurately reflect action shown in figure.
Added new Figure 14 (Pull Coil into Cartridge) immediately after Step #21 and added "(see Figure 14)" to the end of Step #21. Renumbered subsequent Figures accordingly.	To improve usability by providing a new image showing how to pull the Coil into the Cartridge.
Added new Figure 15 (Advance Coil Until Fluoroscopy Marker Band Enters Cartridge) immediately after Step #23 and added "(see Figure 15)" to the end of Step #23. Renumbered subsequent Figures accordingly.	To improve usability by providing a new image showing how to advance the Coil into the Catheter.
Revised Step #24 as follows: **From:** "Turn on fluoroscopy when the fluoroscopy marker band (on the Forceps shaft) enters the Cartridge".	Added the word "black" to provide additional clarification regarding the marker band on the Forceps.

Description of Change	Reason for Update
To: "Turn on fluoroscopy when the black fluoroscopy marker band (on the Forceps shaft) enters the Cartridge".	
Revised Step 29(b) as follows: **From:** "If Coil position is not ideal, see **Section 12 – Coil Repositioning Following Deployment**". **To:** "If the Coil has been placed proximal to the airway, continue to place Coils and reassess placement after placement of the last Coil. If the proximal end of the Coil is pressing into the tissue as shown in **Figure 18**, reposition or redeploy the Coil". Also moved previous Step 29 (b) and made it new Step 29(c) and included reference to Figure 19.	Added clarity for reader regarding proper Coil positioning.
New Figure 19 (Example of Optimal Coil Placement) showing more distal placement of the Coil so the proximal ball of the Coil is not visible.	Added clarity for reader; improved photo.

Changes to Section 13.0 – Bronchoscopic Coil Removal Following Implantation

Description of Change	Reason for Update
Remove table format and put into text format.	To improve usability.
Revised 1st warning to add "(e.g., persistent pleuritic pain") as a specific example of a reason for Coil removal.	Added clarity for reader through addition of specific example for coil removal.
Warning regarding Coil removal split into two separate warnings to better present information and bolding the words "**after 2 or more months**". Remove "granulation" and add "regrowth". Also added "If bronchoscopic removal is not possible, surgical removal using a thoracoscopic approach can be considered".	Added clarity for reader.
Remove existing Note ("Note: If possible, always try to remove the Coil using bronchoscopic techniques before considering other methods") because it is redundent considering new text added to Warning ("If bronchoscopic removal is not possible, surgical removal using a thoracoscopic approach can be considered").	Improved readability through reduction of redundancy.

Description of Change	Reason for Update
Revised procedural Step #1: **From:** To perform Coil removal, you must have a 2.0mm working channel bronchoscope with a 65cm maximum working length. **To:** To perform bronchoscopic Coil removal subsequent to the implantation procedure, you must have a therapeutic bronchoscope with a minimum 2.0mm inner diameter working channel and a 65cm maximum working length. Also removed space between “2.0” and “mm”.	To agree with Note (regarding therapeutic bronchoscope requirement) contained in Section 4.2 - Coil Removal Warnings, and Section 8.1 – Materials Required.

Changes to Section 15.0 – Trademarks

Description of Change	Reason for Update
Changed email address: **From:** CS@btgplc.com **To:** pneumrx@btgplc.com	Previous email address had inappropriate routing.