BTVA®

Bronchoscopic Thermal Vapor Ablation (BTVA®) Patient Selection Patient Management & Treatment Centres in Europe

Guide for Referring Physicians

Uptake Medical®

A Broncus Company

PATIENT SELECTION (NON-INVASIVE TREATMENT)

Do you have patients who suffer from severe emphysema, specifically from heterogeneous upper lobe emphysema? Do your patients complain about weakening conditions regardless of optimal medical management? For patients who desire to improve breathing and quality of life, there are different treatment options which may relieve their symptoms.

One of these options is Bronchoscopic Thermal Vapor Ablation (BTVA®), a non-surgical, non-implant therapy which is effective(*) for patients with heterogeneous upper lobe emphysema. BTVA® reduces diseased emphysema segments with a controlled spray of precisely targeted vapor and selectively ablates only the diseased lung tissue segments. The decision regarding the optimal intervention for your individual patient can be made by one of the expert treatment centres in this brochure. Your referral may result in positive patient outcomes

BTVA® TREATMENT

The volume reduction of diseased lung segments with BTVA can allow for better breathing. BTVA is the first personalized treatment for emphysema that allows targeted treatment of a patient's most diseased emphysema segment. A BTVA vapor catheter is guided through bronchoscope into the airways to the diseased segment and a precise, patient-specific, dose of vapor is delivered. This painless vapor dose is delivered in 3 to 10 seconds, ablating the targeted portion of diseased tissue causing a natural, gradual reduction occurring over several weeks, significantly reducing the risk of potentially life-threatening pneumothorax while sparing healthier segments from being unnecessarily treated. Reduction of diseased, overinflated segments allows healthier segments to expand and the diaphragm to unflatten-improving breathing, and quality of life. BTVA is not associated with the potential long-term complications posed by implants.

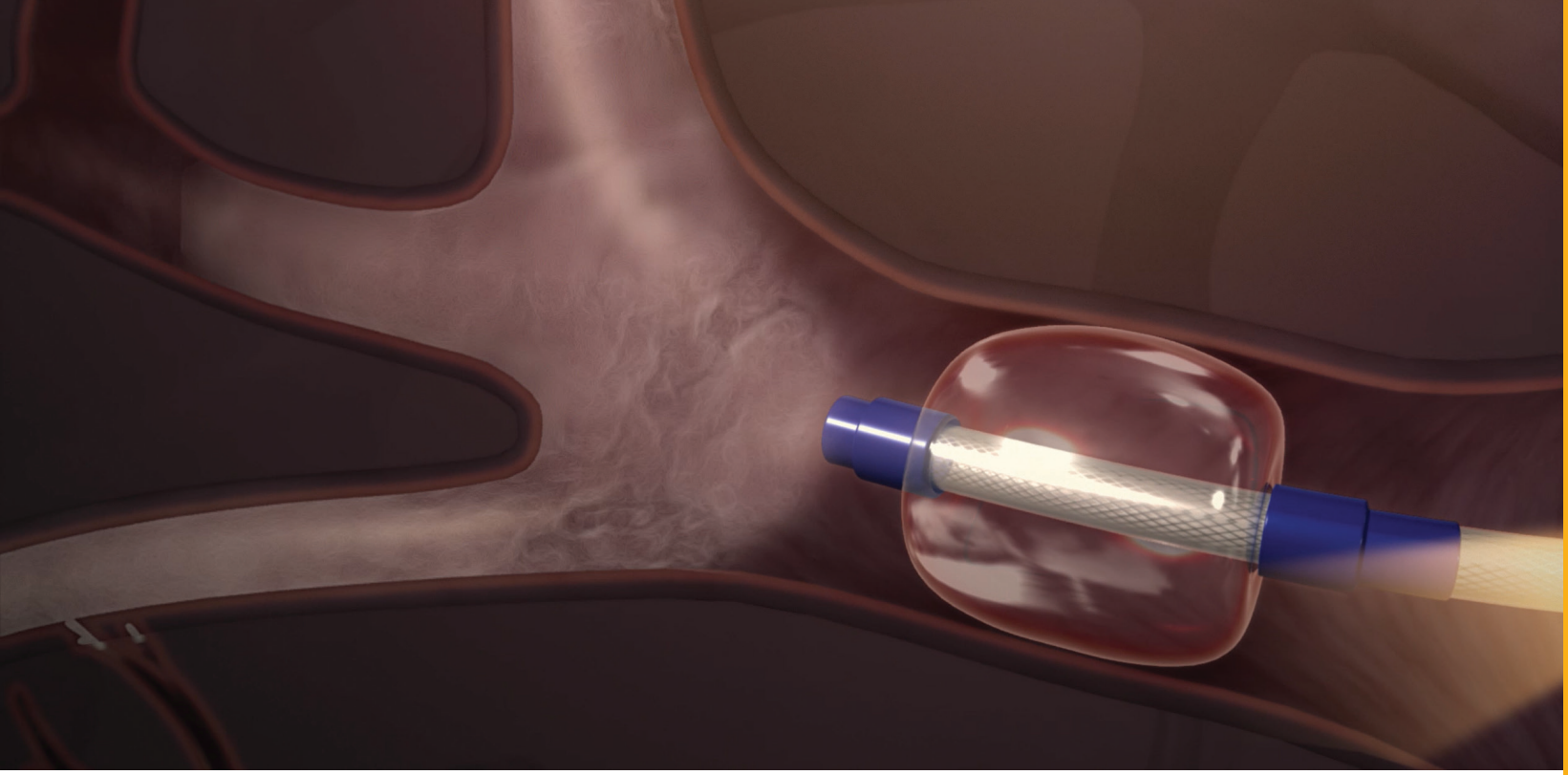
SELECTION CRITERIA FOR BTVA®

PRE-SCREENING EMPHYSEMA PATIENTS FOR BTVA TREATMENT:

Your patient is:

- Severe (diagnosed with emphysema III or IV)
- Stable (no recent or recurring infections or exacerbations)
- Symptomatic (despite optimal medical management worsening dyspnea)
- Review and consider all available medical and therapeutic options for the patients, including other treatments for lung volume reduction (LVR).
- Does not have an increased risk of bleeding (including drug induced, e.g. oral anticoagulation or platelet aggregation inhibitors).

*Lancet Respir Med 2016; 4:185-93 and Respiration DOI: 10.1159/000489815



IFU CRITERIA:
Patients will be prescribed InterVapor according to the IFU. The following guidelines should be used for patients considered for InterVapor® treatment and entry into the registry:

Inclusion criteria:
Patients will have heterogeneous emphysema, as evidenced by high-resolution computed tomography (HRCT) and who are not responding to optimal standard of care medical treatment (including rehabilitation).

Exclusion criteria :

- Patient has to tolerate bronchoscopy
- Concomitant illnesses or medications that would pose a significant increased risk for complications following treatment with InterVapor. Examples of particular relevance include: immune system disorders, immunosuppressant medications of clinical relevance, bleeding disorders and unstable cardiovascular conditions, history of asthma or alpha 1 antitrypsin
- Newly prescribed morphine derivatives within the last 4 weeks
- Bacterial infection or symptoms indicative of active infection (i.e., fever, elevated white blood cell count)
- Presence of single large bulla (defined as > 1/3 volume of lobe) in the upper lobe
- Recent respiratory infections or COPD exacerbation in preceding 6 weeks

The safety and efficacy of the InterVapor procedure has not been established in the following patient populations and should be considered for exclusion upon physician discretion:

- Forced Expiratory Volume in 1 second (FEV1) < 20% predicted
- DLCO < 20% predicted
- Pulmonary hypertension (mean PAP>35mmHG)
- Body mass index (BMI) < 18kg/m2 or > 32 kg/m2
- Heart and/or lung transplant, lung volume reduction surgery (LVRS), bullectomy, or thoracic surgery with removal of lung tissue
- Patients with current endobronchial valve(s), or with explanted endobronchial valves where there is obvious airway obstruction in a segment targeted for InterVapor. Patients with endobronchial coil implants. Patients with previous endobronchial polymer/glue treatment
- Recent respiratory infections or COPD exacerbation in preceding 6 weeks
- Unstable COPD (any of the following):
    - > 3 COPD related hospitalizations requiring antibiotics in past 12 months
    - COPD related hospitalization in past 3 months
    - Daily use of systemic steroids, i.e. > 5 mg prednisolone
- Inability to walk > 140 meters in 6 minutes (6MWD) following optimised medical management
- Homogeneous disease
- Clinically significant bronchiectasis

PATIENT MANAGEMENT

Prior to the InterVapor® procedure patients should:

- Discontinue anticoagulant, non-ASA anti-platelet medication and ASA medication (i.e. aspirin)>100mg prior to procedure.
- Limit or stop prophylactic ASA anti-platelet medication (eg. aspirin) dosage ≤ 100mg per day per hospital standard of care
- Continue their usual optimised medications including inhaled respiratory medications
- Receive an inhaled short-acting beta-agonist +/- acting anticholinergic
- Receive prophylactic broad spectrum antibiotics the day of InterVapor® procedure

Post InterVapor® procedure patients and/or physicians should:

- Avoid anticoagulant and non-ASA anti-platelet medication or prophylactic ASA medication (i.e. aspirin)>100mg for at least 6 weeks post-procedure
- Limit use of ASA anti-platelet medication ≤ 100mg per hospital standard of care
- Continue prophylactic broad spectrum antibiotics > 14 days
- Remain active and be encouraged to incorporate regular physical activity
- Be monitored at frequent intervals during the first 6 weeks for clinical status, with continued monitoring over the subsequent two to four months
- Be aware that expected changes in the lungs over the first 2 to 4 weeks may be accompanied by symptoms (e.g. cough, sputum, hemoptysis, dyspnea, fever, fatigue, chest discomfort) of varying severity. If moderate to severe symptoms occur, patients should be informed to contact their treating physician. In clinical trials, physicians have treated patients with moderate to severe symptoms with increased bronchodilators, antibiotics and steroids.
- Review discharge CT/X-Ray for signs of infiltrates or pneumonia.

Physicians should be aware that radiographic changes are typical and occur quickly in the treated area. Other etiologies (e.g. infection) should be considered when radiologic changes in non-treated areas are observed.

NOTES

Bronchoscopic Thermal Vapor Ablation (BTVA®) treatment included in the 2020 GOLD Guidelines

GOLD GUIDELINES 2020

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