

VividTrac®

Single Use Video Intubation Device



Open System - Single Use Video Intubation Device, utilizing standard USB II interface that works on Windows based or MAC computer, and Android Tablets, with NO proprietary system cost.

Superior Imaging - Wide Angle, High Resolution, Digital Video of airway displayed on the computer screen allows the user to Store, Display on TV, Transmit or Broadcast over WiFi or 3G networks, with off-the-shelf computing and connectivity solutions.

NO Head Tilt - Blade tip positions easily at the epiglottic vallecula to facilitate direct visualization of the cords, with the patient in any position.

NO Stylet and Concurrent Suction - Integrated ETT Channel guides the ETT precisely through the vocal cords and trachea without the need for a Stylet. Right hand is free to apply suction concurrent to intubation.

NO Batteries - 100% powered through USB cable, with

Anti-fog - Automatic anti-fogging camera.

Portable and Affordable - NO Cleaning, NO Maintenance, Recyclable.

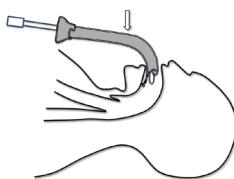
Vivid Medical Inc.

Vision to Help Save Lives

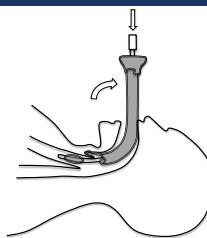


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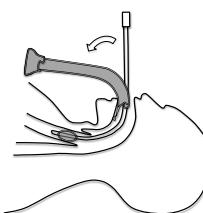
1.



2.



3.



SIZES

ETT 6.0mm-8.5mm

ETT > 8.5mm (see adjunct devices)

DESCRIPTION

VividTrac is a Single Use, Video Intubation Device that works on many computer systems equipped with USB II port as a Standard USB Camera, using available video camera applications on Windows, Mac and Linux systems. Alternatively, an automated video display software (VividVision) can be downloaded, at no charge from: www.VividMed.com.

Be sure to confirm the interoperability of the VividTrac with your computer's video display software before engaging with a patient.

CLINICAL NOTES

VividTrac is provided in a Medically Clean package. If package is damaged in any way, discard the device and use a new one.

The ETT can either be preloaded in the VividTrac tube channel (up to where the ETT tip is visible on the right side of the video image), or inserted into the VividTrac tube channel once visualization is achieved. Load lubricated ETT from the top of the VividTrac. To avoid the ETT from slipping out of the channel, load it with the natural curvature of the tube facing inward in the channel.

There is no need for head tilt or jaw thrust when using the VividTrac. VividTrac does not have a handle like a laryngoscope. To insert, VividTrac can be held from its proximal end (Top), allowing for the entire body of the device to be inserted into the oral cavity.

VividTrac is versatile and can support use of adjunct devices depending on the anatomy of the patient, skill level or preference of the user, or as necessary (See "Using Adjunct Devices with VividTrac")

VividTrac can be used on a patient with simultaneous chest compressions during CPR, or if a patient is actively seizing.

In cases where visualization is obscured by saliva or blood:

- Clear the airway by applying suction if necessary
- If there is liquid or debris on the lens of the camera, blocking or blurring visualization, remove VividTrac and aggressively tap the VividTrac metal tip onto a clean hard surface a few times to clear the view, before retrying.

INSTRUCTION FOR USE

1. ET Tube Size

VividTrac Adult size accommodates ETT sizes 6.0mm-8.5mm.

For ETT with oversize OD (Outside Diameter), the ETT can be placed outside the VividTrac ETT channel using adjunct devices.

2. Connection of Device

Connect the USB cord of the VividTrac to the USB port of display computer confirming live video from VividTrac is displayed and the illumination LED is turned on. Optionally USB extension cord can be utilized.

3. VividTrac Insertion

Note: VividTrac is inserted more like an Oral Airway device (or LMA) rather than a laryngoscope blade. Gently hold the proximal end of VividTrac using fingertips, with the index finger on the top surface, next to the preloaded ETT and USB cord.

While looking at the patient, insert VividTrac into the mouth (midline) until the VividTrac body rests on the chin of the patient and parallel to the patient's neck (see image #1). If required use your free hand's thumb to lift the tongue out of the way, allowing the blade tip to pass the base of the tongue. Advance VividTrac deep into the oral cavity in a sweeping motion, following the roof of the mouth, pushing gently with the index finger on the top surface of the device.

INSTRUCTION FOR USE (CONT.)

4. Alignment and ETT Placement

Looking at the video image gradually advance the VividTrac into the patient's mouth until the patient's vocal cords come into view. VividTrac will self align, when the blade tip is placed under the epiglottis (similar to a Miller blade). If the VividTrac blade tip is placed in the vallecula (similar to a MAC blade), a slight pull of the VividTrac proximal end towards you, will lift the epiglottis out of the way. (Image #2)

Slight positional adjustments can be performed if necessary by rotating VividTrac body around its vertical axis (for left and right alignment), or adjusting the insertion depth of the VividTrac (for up and down alignment). You can start advancing the ETT in the tube channel (with your right hand) as soon as the epiglottis and/ or vocal cords are visible. Do not Press the VividTrac metal tip into the Vocal Cords. Continue advancing the ETT in the trachea until the cuff is visualized passing through the vocal cords.

5. VividTrac Removal, Secure and Check

Separate the ETT from the top of VividTrac tube channel by pushing the tube forward and to the right.

Secure the ETT in place at the corner of the mouth with the right hand, while gently reversing the path of insertion (midline) and withdrawing the VividTrac out of the oral cavity with the left hand (see image #3)

Inflate the cuff, secure the airway and mark the tube position.

In the case where ETT placement needs reconfirmation, pass the ETT to the left corner of the mouth, and re-insert VividTrac (midline) to directly visualize the vocal cords and ETT placement.

USING ADJUNCT DEVICES WITH VIVIDTRAC

A. Use of Bougie with ETT inside the VividTrac tube channel

Preload the ETT inside the VividTrac tube channel and insert the device into the patient's oropharynx as per instructions above. Insert the bougie directly into the ETT and guide through the vocal cords into the trachea. Then gently advance the ETT over the bougie until the cuff is visualized passing through the vocal cords. If you experience any resistance while advancing the ETT, release the ETT from the tube channel (without pulling the bougie out from the trachea), and then gently advance the ETT until the cuff has passed the vocal cords.

Remove the bougie, confirm placement of the ETT, and then remove the VividTrac as described above.

B. Use of Bougie with Larger Size ETT

Insert bougie in the VividTrac tube channel instead of an ETT. Follow instructions above using the bougie in place of the ETT. Once the bougie has passed the cords and is inside the trachea, take bougie out of the channel and remove the VividTrac. Then thread the larger size ETT over the bougie.

C. Use of ETT outside the VividTrac tube channel utilizing a Stylet

Insert the VividTrac with no ETT into the patient's oropharynx as per instructions above. Once the vocal cords are visualized, separately insert a stylet loaded ETT alongside the VividTrac (outside the tube channel) to intubate.

Remove the stylet, confirm ETT placement, and then remove the VividTrac as described above.



Refer to www.VividMed.com for recycling instructions