

VividTrac[®]

Video Intubation Device

INSTRUCTIONS FOR USE

English

www.VividMed.com

Manufactured in the USA by:

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DESCRIPTION

VividTrac is a Single Use, Video Intubation Device that is available in both Adult and Pediatric models.

VividTrac works on a variety of common computers, tablets and other systems equipped with USB II HOST port capability, as a Standard USB Video Camera.

A generic video camera software application, or Vivid Medical's VividVision® software can be used on variety of operating systems to display video, take snapshots or record the procedure using the VividTrac (for more information please go to www.VividMed.com).

Be sure to confirm the interoperability of the device with your computer or tablet as well as the video display software you intend to use before engaging with a patient.

VIVIDTRAC SIZES

VividTrac Adult:

ETT sizes 6.0mm - 8.5mm
for ETT > 8.5mm (see adjunct devices)

VividTrac Pediatric:

ETT sizes 4.0mm - 6.0mm

Accessory:

Lubricating Jelly, 2.7g Packet

CLINICAL NOTES

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

VividTrac has an integrated ETT channel for tube guiding and does not require a Stylet. VividTrac blade is anatomically shaped, thus there is no need for head tilt or jaw thrust when using the VividTrac. VividTrac does not have a handle like a Direct 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, if needed.

VividTrac is versatile and can support use of adjunct devices depending on the anatomy of the patient, skill level, user preference, or as necessary (See “Using Adjunct Devices with VividTrac”). For ETT with oversize OD (Outside Diameter), the ETT can be placed outside the VividTrac ETT channel using adjunct devices.

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.

INSTRUCTIONS FOR USE

1. Connection of Device

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

2. Preload ETT into the VividTrac Tube Channel

Preload a lubricated ETT from the Proximal end (Top) of the VividTrac tube channel (Figure 1).

NOTE: Lubricate the ETT especially around the cuff area.

NOTE: To avoid the ETT from slipping out of the channel during loading, load it with the natural curvature of the tube facing inward in the channel (Figure 1a). Insert ETT to where the ETT distal tip is just visible on the right side of the video image (Figure 1b).

3. Holding of Device

Gently hold the proximal end of the VividTrac using only your fingertips (right hand or left hand), with the index finger on the top flat surface of the device (next to the preloaded ETT and USB cord), and your thumb and middle finger on either side of the device (Figure 2).

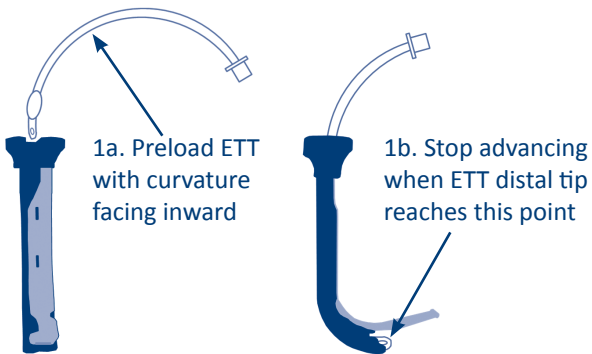


Figure 1, Preload ETT

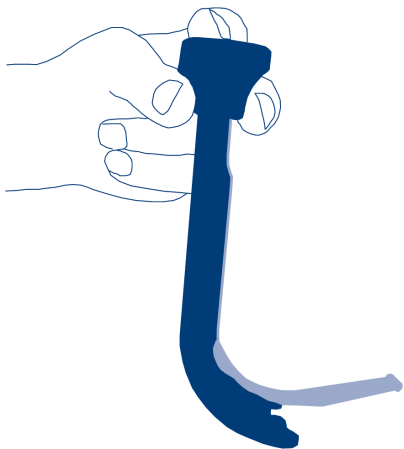


Figure 2 , Hold VividTrac with Finger Tips

4. VividTrac Insertion

While looking inside the patient's mouth, with the VividTrac body horizontal and the Metal Blade Tip facing directly downward, insert the VividTrac blade midline into the mouth, until the VividTrac body rests horizontally on the chin of the patient, as depicted in Figure 3.

NOTE: If required use your free hand's thumb to open the mouth and lift the tongue out of the way.

NOTE: Do not insert the VividTrac into the airway if liquid or blood is present (use suction before using the VividTrac).

With the VividTrac resting on the patient's chin and the blade tip positioned below the tongue, look at the video image and gently start advancing the VividTrac body further into the oral cavity. Make sure the VividTrac blade stays midline, picking up the tongue as it reaches the epiglottis. This movement is accomplished by lightly pressing the proximal end of the device towards you and continuing with the insertion until the device body is positioned nearly vertical (Figure 4).

NOTE: Make adjustments during insertion to assure the blade tip sweeps under the tongue.

NOTE: Suction can be applied concurrently if necessary from the right side of the VividTrac device during the insertion

Once the VividTrac body is near the vertical position (Figure 4) the patient's airway should come into view as depicted in Figure 5.

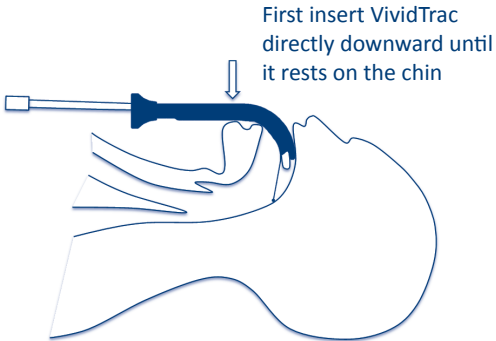


Figure 3, Insert with VividTrac Blade Straight Down

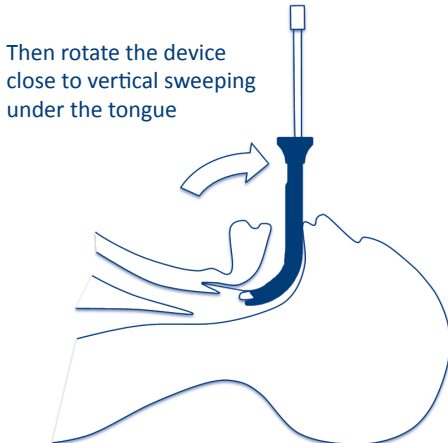


Figure 4, Hold VividTrac Body Vertical

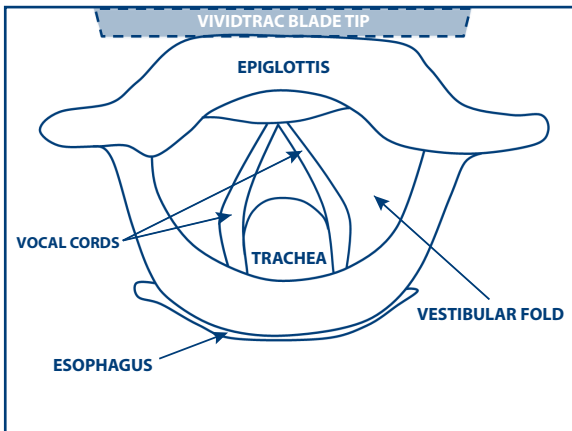


Figure 5, Center the Airway in the Center of the Screen

NOTE: VividTrac is anatomically shaped and inserted more like an Oral Airway device (or LMA) rather than a laryngoscope blade.

NOTE: Best alignment for targeting the ETT towards the trachea, is when the vocal cords are centrally positioned in the image (Figure 5).

5. Alignment and ETT Placement

VividTrac will align itself (with image of airway at the center of the display), when the blade tip is placed centrally under the epiglottis (similar to a Miller blade), or when placed in the vallecula (similar to a MAC blade). To obtain a full view of the airway it is recommended to hold the body of the device close to the vertical position (as depicted previously in Figure 4).

NOTE: Do not “Lift Up” with the VividTrac to gain better visual access to the airway, as you would with a Direct Laryngoscope.

Alignment and placement of ETT is a concurrent two handed operation, by holding the VividTrac with the left hand and manipulating the ETT with the right hand.

Start advancing the tube with your right hand as soon as the airway comes into view, while using your left hand to align the VividTrac device. Maintain a generous amount of space in front of the camera for the ETT to approach the airway from the right side of the image directly towards the vocal cords.

NOTE: Do not press or position the VividTrac metal tip too close to the vocal cords at any time.

NOTE: Hold VividTrac back from the airway, and maintain a position where the Epiglottis, Vestibular fold, and esophagus are all fully visualized within the image (as depicted in Figure 5).

NOTE: Insert the VividTrac body deeper into the oral cavity for larger size patients and more anterior airways.

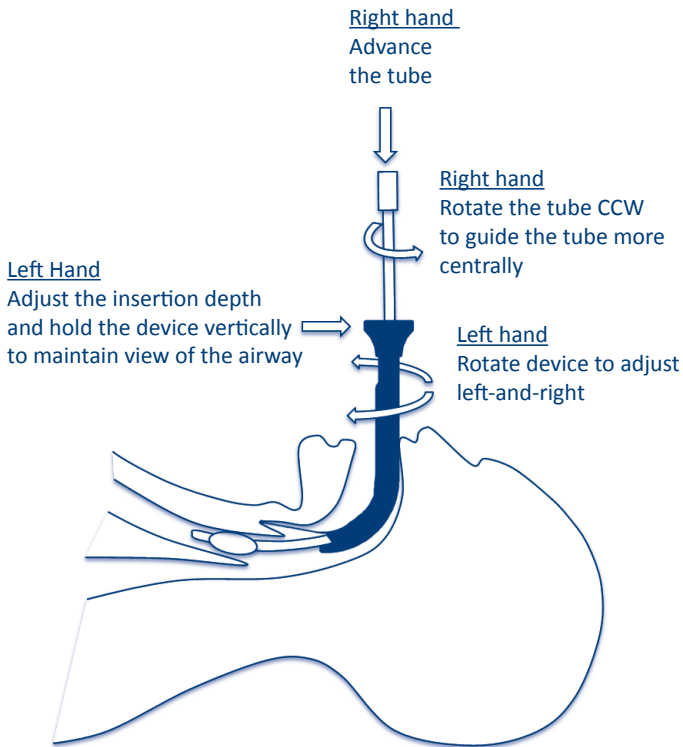


Figure 6, Minor Alignment and Tube Insertion

5.1 Fine Alignment Tips (Figure 6):

Using the Left Hand (holding the VividTrac)

- Gently moving the VividTrac's proximal end towards you (closer to a vertical position) will allow the blade to lift the epiglottis and other soft tissue out of the way and gain a more complete view of the vocal cords.
- Slight adjustments in the insertion depth of the VividTrac allows for up-and-down alignment of the ETT with respect to the vocal cords.
- Rotate the VividTrac device slightly in the left-and-right direction to center the vocal cords on the image.

Using the Right Hand (holding the ETT)

- While advancing the ETT, slight rotation of the ETT inside the VividTrac channel in the counterclockwise direction will further point the ETT towards the left.

NOTE: Advancing the ETT more quickly, will direct the ETT tip closer to the tip of the Blade (more anterior).

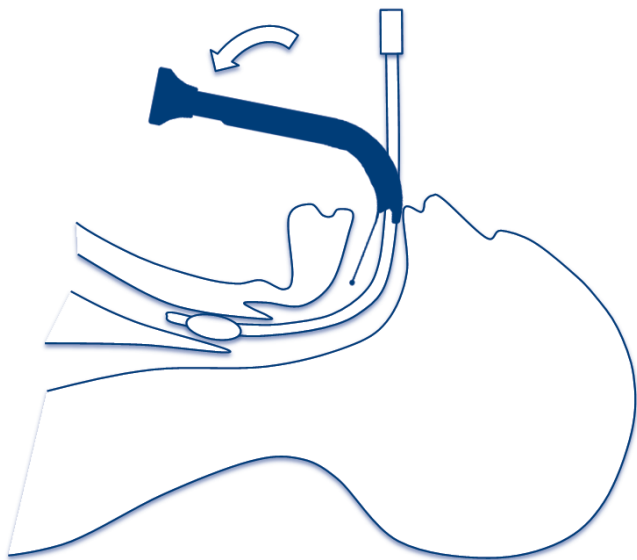


Figure 7, Gently Withdraw VividTrac

6. VividTrac Check, Secure and Removal

Once the ETT cuff is visualized passing through the vocal cords, separate the ETT from the top of VividTrac tube channel, by pushing the proximal end of the tube forward and to the right.

Securely hold ETT at the corner of the mouth with the right hand. Using the left hand gently reverse the path of insertion by withdrawing the VividTrac out of the oral cavity midline, as depicted in Figure 7.

NOTE: VividTrac metal tip is withdrawn when the device body is brought back to horizontal position and parallel to the patient's neck, similar to the position at the start.

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

NOTE: In cases where ETT placement needs reconfirmation, move the ETT to the left corner of the mouth, and re-insert VividTrac midline to once again visualize the vocal cords and the ETT placement.

USING ADJUNCT DEVICES

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 and into the trachea. Then gently advance the ETT over the Bougie until the cuff has passed through the vocal cords. If you experience any resistance while advancing the ETT, release the ETT from the tube channel (taking caution not to pull the Bougie out from the trachea), and then gently advance the ETT until the cuff has passed through the vocal cords.

Remove the Bougie and secure the ETT, then remove the VividTrac midline as described above.

B. Use of Bougie with Larger Size ETT

Insert the Bougie in the VividTrac tube channel (instead of an ETT), making sure it stays inside the channel. Follow the instructions above using the Bougie in place of the ETT. Once the Bougie has passed through the vocal cords and is inside the trachea, release the Bougie from the VividTrac channel without pulling the Bougie out of the trachea. Thread the larger size ETT over the Bougie and into the trachea until the cuff is visualized passing through the vocal cords.

Remove the Bougie and secure the ETT, then remove the VividTrac midline as described above.

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 ETT channel, as you normally would in Direct Laryngoscopy), advancing the ETT until the cuff is visualized passing through the vocal cords.

Remove the Stylet and secure the ETT, then remove the VividTrac midline as described above.

NOTE: For ease of guiding, form the Stylet loaded ETT in a similar shape as the VividTrac blade curvature.

WARNINGS AND PRECAUTIONS

To Maintain Compliance:

- This product should only be used by personnel trained in intubation and use of endotracheal tubes.
- VividTrac users are encouraged to be trained on specific skills necessary in use of the VividTrac.
- Do not sterilize the VividTrac.
- Do not submerge the device in liquids.
- Use only with non-flammable anesthetics.
- Do not put pressure on the teeth with the VividTrac.
- Do not force the VividTrac into the upper airway.
- Preferred storage temperature (0°C to 40°C).
- For control of potential biohazard exposure, recycle per local regulations after use. For Volume Recycling program please contact Recycle@VividMed.com.
- If lubricant jelly comes in direct contact with the eye, it may cause irritation.
- For electrical safety, while VividTrac is used on a patient the computer or tablet used must maintain one of the following conditions:
 - A) The computer or tablet is a Medical Grade device with isolated USB port and/or isolated power adapter.

B) The computer or tablet has a battery source, and is not directly connected to the A/C power while VividTrac is used on a patient (computer or tablet must be charged in-between procedures or using a wireless charger).

C) A separate medical grade USB isolator is used between the VividTrac and the computer/tablet.

- Use an Active, High Speed USB II extension cable if additional cable length (over 10 ft) is required (note: VividTrac device ID may be changed by the Active USB extension cable, in software).
- Sample Training Videos can be found at:
www.VividMed.com

	<p>Single Use</p>
	<p>European CE Mark</p>
	<p>Class A digital device</p>
	<p>Instruction for Use www.VividMed.com</p>
	<p>Vivid Medical, Inc. Palo Alto, CA, USA</p>
	<p>Not made with natural rubber latex</p>
	<p>By Prescription ONLY</p>
	<p>Type B, Electric Shock Protection Maximum Voltage: 5V</p>
	<p>Recycle per Instructions www.VividMed.com</p>

MANUFACTURER'S WARRANTY

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a COMMERCIAL environment. This equipment generates, uses, and can radiate radio frequency energy and may cause harmful interference to radio communications. Operation of this device in a residential area may cause harmful interference with other equipment, in which case the user will be required to correct the interference at his own expense.

The manufacture warrants the VividTrac against faulty materials or manufacturing defects as a SINGLE USE device (or until the expiration date, whichever comes first), provided that the VividTrac is used in accordance with the procedures set forth in these instructions, in a Class A COMMERCIAL environment. This warranty is applicable only if the VividTrac is purchased from an authorized distributor.

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