

Zvu® *High Resolution Anorectal
Manometry Probe*

**Anorectal Manometry Procedure Kit
Instructions for Use**

**Diversatek Healthcare
Technical Research & Training
Center**

9150 Commerce Center Circle, Suite 500
Highlands Ranch, CO 80129 USA

P 800.558.6408 or 303.470.7020

DiversatekHealthcare.com

Part Number: HRAM-194 Rev C
ECO 221-049

HRaM Balloon Attachment and Removal Instructions

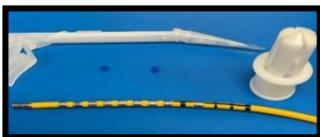
The Zvu® High Resolution Anorectal Manometry (HRaM) Probe utilizes a single-use balloon that must be replaced for each patient study. Special care must be taken when attaching and removing the balloon to keep from damaging the Probe and ensuring the balloon is properly positioned and securely held in place.

Diversatek Healthcare has developed special tools that when used properly will minimize the chance of damaging the Zvu® Probe. This document describes how to use these tools properly.

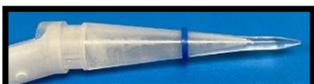
The kit includes:

- One (1) Zvu® Anorectal Balloon
- Two (2) Balloon Retention Bands
- One (1) Band EZ-Removal Guide
- One (1) Band Removal Knife

HRaM Balloon Attachment Steps



1. Gather equipment:
 - a. One (1) Zvu® Anorectal Manometry (HRaM) Probe
 - b. Two (2) Balloon Retention Bands
 - c. One (1) Zvu® Anorectal Balloon
 - d. One (1) Ligator (Part No. HRAM-LIGATOR, sold separately)



2. Insert the loading cone into the ligating drum of the Ligator and slide one band part way up.



3. Place the base of the Band Pusher on a flat surface.
4. Insert the tip of the loading cone into the center of the Band Pusher fingers.



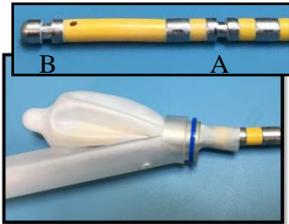
5. Push the Ligator straight down so the fingers of the Band Pusher move the band up the loading cone and onto the ligating drum



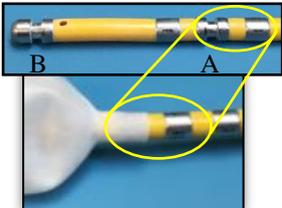
6. Remove the loading cone from the Ligator.



7. Insert the tip of the Zvu[®] Probe into the Zvu[®] Anorectal Balloon.



8. Insert the Probe and Balloon into the lumen of the ligating drum and locate over slot A.

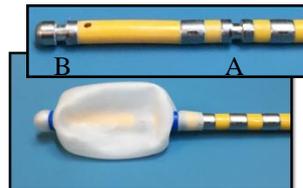


9. Position the end of the balloon so it is between slot A and the rectal sensor. Make sure the balloon neck is not covering the rectal sensor.



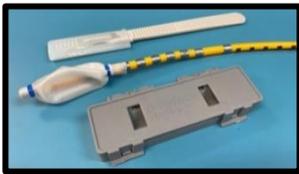
10. Check the alignment of the tool with the slot and avoid releasing the band over a sensor as this may damage the sensor.

11. Squeeze the trigger on the handle of the Ligator to release the band into the slot. Check to ensure the band is properly seated.



12. Follow steps 2 through 6 for applying a second band in slot B.

HRaM Balloon Removal Steps



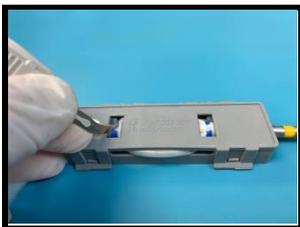
1. Gather equipment:
 - a. One (1) Zvu® Anorectal Manometry (HRaM) Probe with Attached Balloon
 - b. One (1) Band EZ-Removal Guide
 - c. One (1) Band Removal Knife



2. Remove the syringe from the lumen and gently squeeze the balloon to empty it of air. Do not cap the lumen until the balloon has been removed.
3. Place the tip of Probe into the EZ-Removal Guide, so that the tip rests against the end wall.



4. Close the lid, making sure the clips snap into place and the bands are accessible through the port holes.



5. Insert the tip of the Band Removal Knife blade under the band and pull upward to execute the cut. Repeat for the second band.



6. Remove the Probe from the EZ-Removal Guide. Slide the balloon off the tip of the Probe. Discard the Balloon and Retention Bands, EZ-Removal Guide and Band Removal Knife according to the facility's biohazard disposal policy.
7. Follow the reprocessing instructions for the Zvu® Probe listed in the IFU.