

Testing Procedure

When working with sheep fallopian tubes, always use proper precautions. These include wearing a protective face mask and latex gloves at all times.

Testing Procedure—Suction

Objective: to determine conditions required to adequately secure the fallopian tube with the syringe.

1. Fill petri dish halfway with water. Place fresh sheep fallopian tube in petri dish for testing. Secure both ends of sheep fallopian tube, leaving enough slack to be able to lift the middle section of the fallopian tube $\frac{1}{2}$ " from the bottom of the petri dish.
2. Extrude syringe tip from device and place in full contact with fallopian tube. Create suction to secure fallopian tube.
3. Lift fallopian tube $\frac{1}{4}$ "- $\frac{1}{2}$ " from petri dish for 10-20 seconds to ensure fallopian tube has been adequately secured. Return fallopian tube to petri dish. A successful trial is one in which suction is created, the tissue is lifted and held for the indicated time, and the fallopian tube is returned to the petri dish without dropping unexpectedly.
4. Visually inspect tissue for any signs of damage that may have been caused by the syringe and record. Damage may range from slight tissue indentation to rupture of the tissue. Tissue should tear no more than 5% of the time.
5. Repeat at a different location on the fallopian tube.
6. Place syringe tip next to fallopian tube, but not in full contact with the tissue. Create suction to determine if device will secure fallopian tube even if full contact has not occurred. Repeat steps 3 and 4.
7. Continue testing at various angles and levels of contact with the tissue to determine minimum amount of contact that is adequate to secure the fallopian tube. Repeat until sufficient trials have been performed. Device should create adequate suction to secure device 95% of the time, so from recorded data, determine what conditions are required to give these results.

Testing Procedure—Banding

Objective: to determine how far push-rod must be twisted to release first and second bands, how often bands release separately, and what percentage of the time banding results in complete occlusion.

1. Fill petri dish halfway with water. Place fresh sheep fallopian tubes in petri dish for testing. Secure both ends of sheep fallopian tube, leaving enough slack to be able to lift the middle section of the fallopian tube $\frac{1}{2}$ " from the bottom of the petri dish.
2. Using band loader, load two bands and the band separator onto the device according to given loading procedure.
3. Extrude syringe tip from device and place in contact with the fallopian tube. Create suction and secure fallopian tube.
4. Twist push-rod until the first band releases onto the fallopian tube. Record how far push-rod must be twisted before first band is released, and whether the separator and/or the second band are released at this step.

5. Release fallopian tube from syringe and visually inspect, looking for incomplete occlusion or damage to the tissue. With a syringe, push water into one end of the fallopian tube. ABSOLUTELY NO water should come out the other end of the fallopian tube; instead, water should back up behind the banded section of the tube, indicating complete occlusion. Record results.
6. Secure a different fallopian tube and twist push-rod until separator and the second band are released. Record how far push-rod must be twisted before these events occur.
7. Repeats step 5 on second fallopian tube.
8. Continue testing until sufficient trials have been performed. Bands should release separately and at the same position (same amount of twisting of the push-rod) 95% of the time. Banding should result in complete occlusion **AT LEAST** 99% of the time.

Testing Procedure—Procedure Reversal

Objective: to determine ease of reversal of procedure, as well as extent of damage to the tissue.

1. Fill petri dish halfway with water. Place fresh sheep fallopian tubes in petri dish for testing. Secure both ends of sheep fallopian tube, leaving enough slack to be able to lift the middle section of the fallopian tube ½" from the bottom of the petri dish.
2. Load device using the band loader according to the given loading procedure.
3. Secure first fallopian tube and release first band. Release the fallopian tube and repeat on second fallopian tube.
4. Repeat steps 1-3 several times, ensuring an adequate number of trials is being performed.
5. Return banded sheep fallopian tubes to original container and store in refrigerator.
6. After (1 day/1 week/1 month), remove banded fallopian tubes from storage and place in a petri dish filled halfway with water.
7. Using surgical scissors, carefully snip the bands to remove from fallopian tubes. Visually inspect fallopian tubes for tissue damage. Damage may range from slight tissue indentation to rupture of the tissue. Record results.
8. In order for the procedure to be easily reversible, there must be very little damage to the tissue. Tissue should tear no more than 5% of the time.

Testing Procedure—Band Loader

Objective: to determine ease of use of banding loader

1. Position first band on band loader.
2. Place tip of band loader against the banding device. Release trigger and remove band loader.
3. Visually inspect band that has been released onto the banding device. In a successful trial, the band will be completely on the device, and it will not be twisted. Record results.
4. Place separator on the banding device.

5. Repeat steps 1-3 for second band to be loaded onto the banding device. Additionally, visually inspect separator and record any damage that may have occurred during band loading.
6. Repeat procedure until sufficient trials have been performed. Successful band loading should take place 95% of the time.