

PROCEDURE FOR USE - MORSAFE TISSUE MORCELLATION BAG

1. Open the sterile packaging of the MorSafe® Tissue Morcellation Bag and Introducer Sheath in a sterile area, remove the separator from the MorSafe® Tissue Morcellation Bag and remove the Introducer Sheath from the separator (Figure 1).

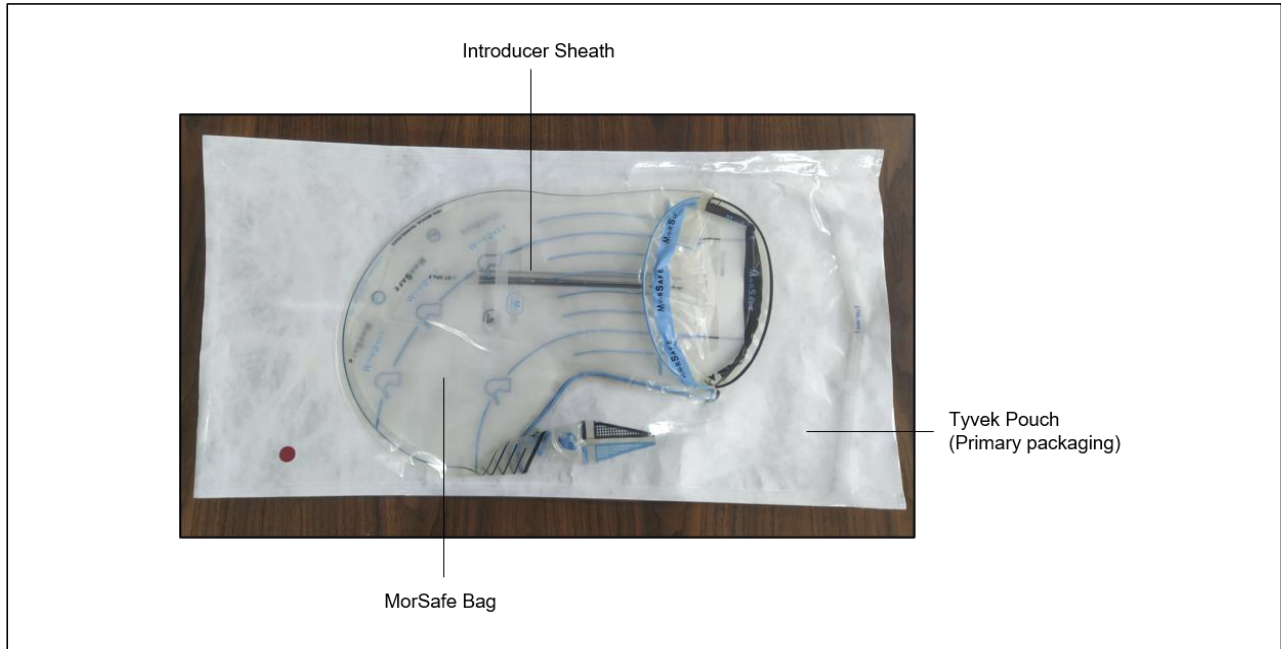


Figure 1: Packaged MorSafe Tissue Morcellation Bag

2. Fold the Morcellation Bag and place it in the Introducer Sheath as shown in Figure 2. Ensure that the Morcellation Bag is slightly outside the Introducer Sheath at the end marked as 'INSERT'. This is to enable pulling out of the Morcellation Bag when it has been introduced in the abdomen.



Figure 2: Folded MorSafe® in the Introducer Sheath

3. Insert the Introducer Sheath with the MorSafe® in the patient through the 15 mm incision as shown in Figure 3.

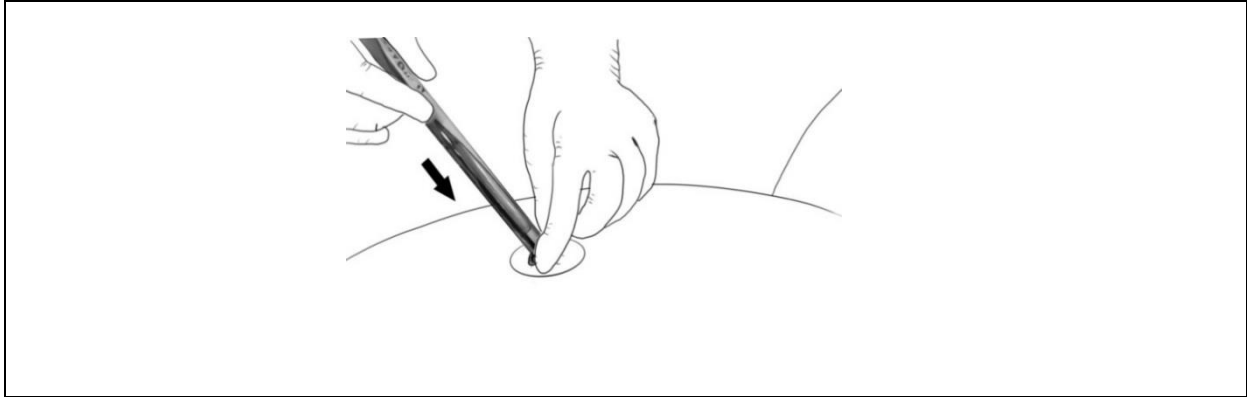


Figure 3: Insertion of Introducer Sheath with MorSafe®

4. Pull the Introducer Sheath out of the incision while simultaneously pulling the MorSafe® Tissue Morcellation Bag in the abdominal cavity.
5. Manipulate the large opening of the MorSafe® Tissue Morcellation Bag using a blunt grasper until the bag opens itself as shown in Figure 4.

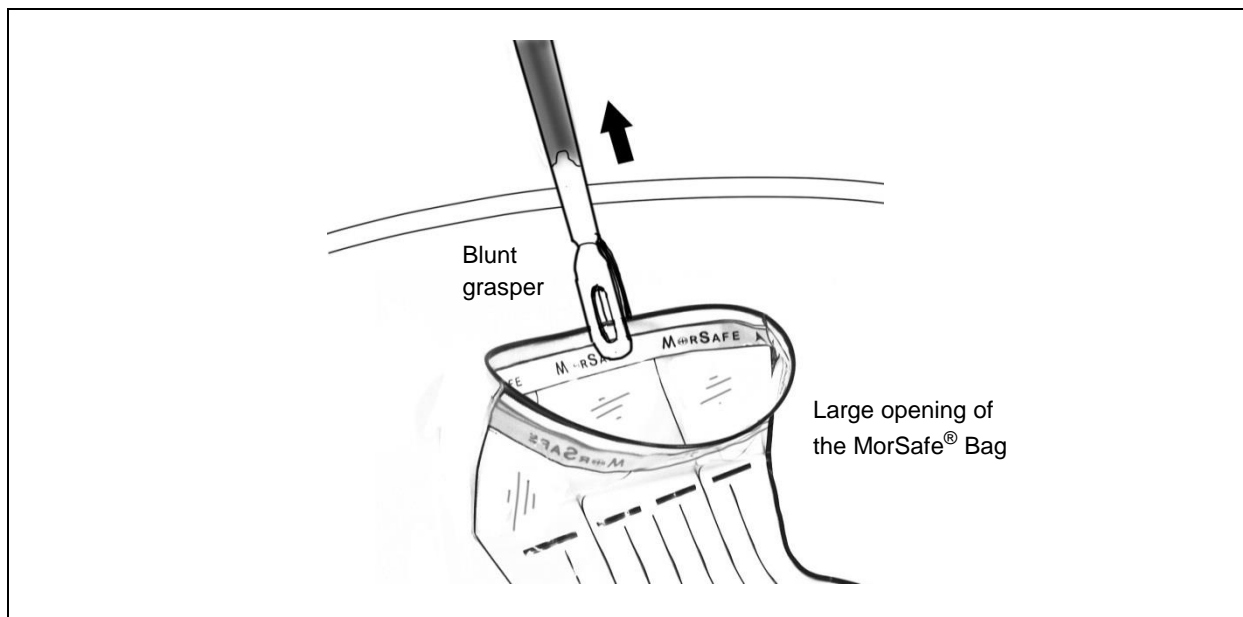


Figure 4: Manipulation of large opening of the MorSafe® Tissue Morcellation Bag

6. In the Model XG-500 when the text 'MorSafe®' in Black is seen on the Blue band or when the text "Morsafe®" in Blue is seen on the Black band just below the opening, it means that this is the inner side of the MorSafe® Tissue Morcellation Bag. Alternatively, the words "Blue Side" and "Black Side" are seen in mirror image and the text 'MorSafe®' on the neck of the opening is not visible when seen from the outside of the Morcellation Bag. This is for the surgeon to distinguish between the inside and outside of the MorSafe® Tissue Morcellation Bag.

7. Grasp the tissue to be morcellated and place it inside the Bag as shown in Figure 5.

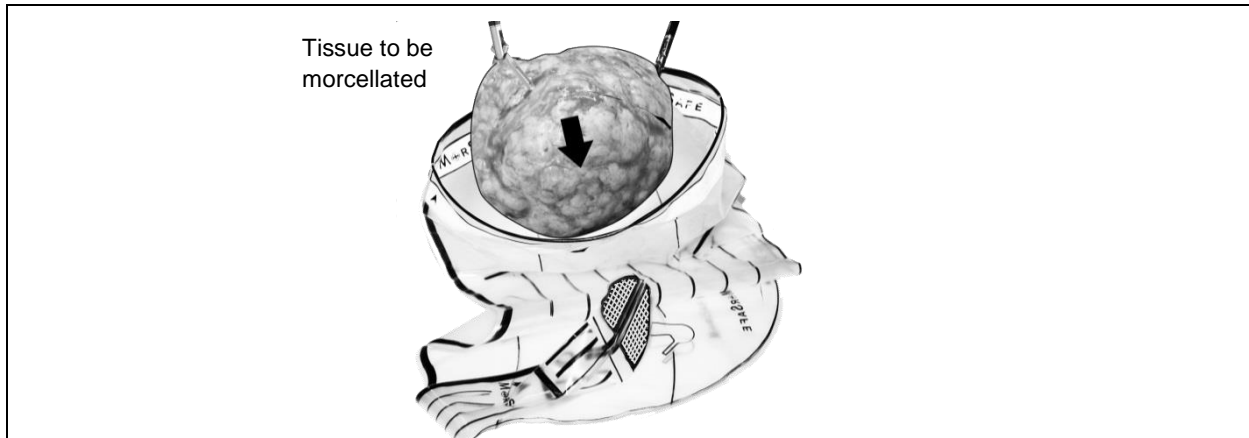


Figure 5: Placement of tissue in the MorSafe® Tissue Morcellation Bag

8. Using blunt graspers, grasp the large opening near the arrow mark as shown in Figure 6.

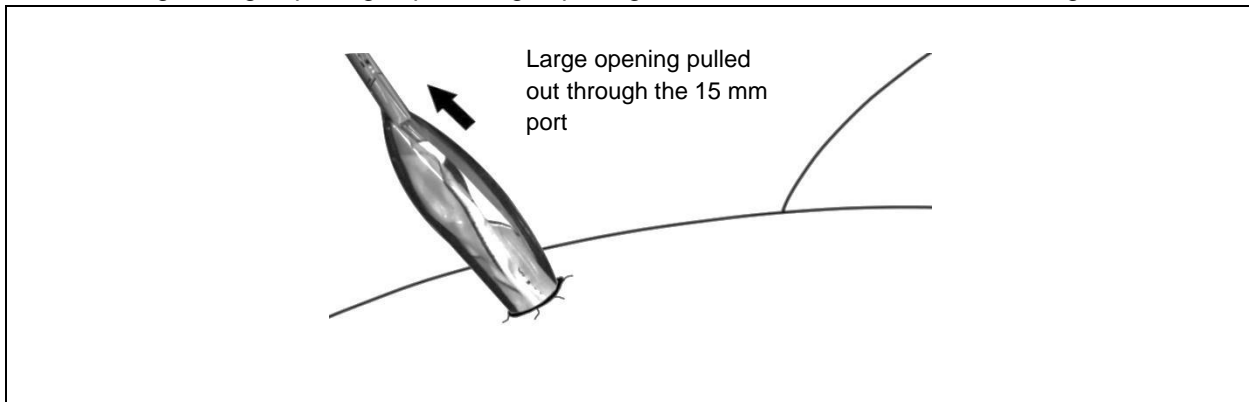


Figure 6: Pulling out the MorSafe® Tissue Morcellation Bag

9. Pull out the MorSafe® Tissue Morcellation Bag XG-500 through the 15 mm port until the bold line is completely outside the body as shown in Figure 7. This will bring the large opening out of the body (Figure 7).

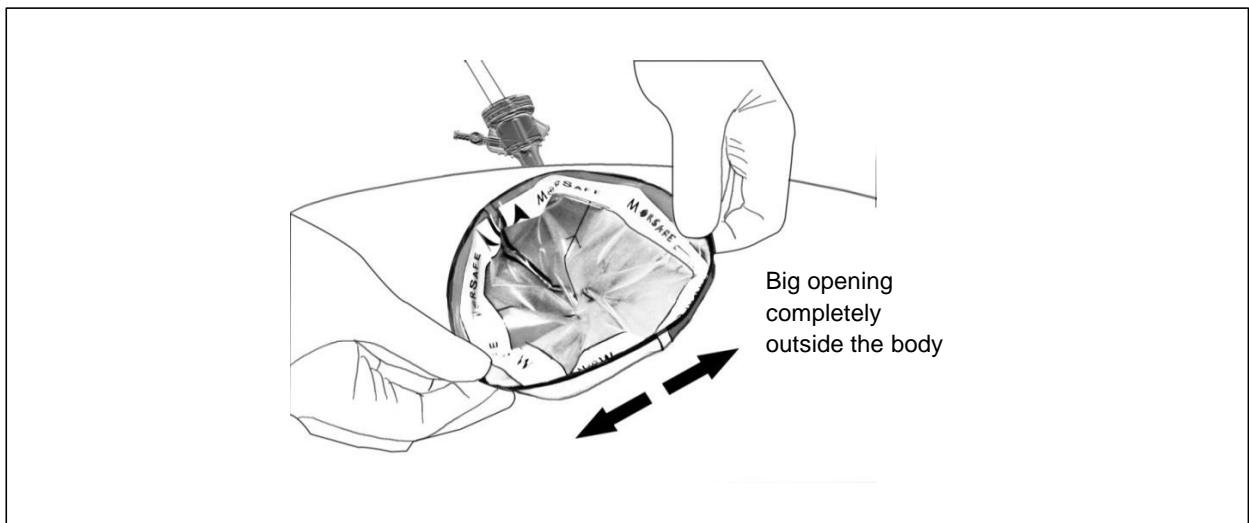


Figure 7: Big Opening of the MorSafe® Tissue Morcellation Bag outside the body

10. Now remove the camera from the umbilical port and insert it through the side port (Figure 8).

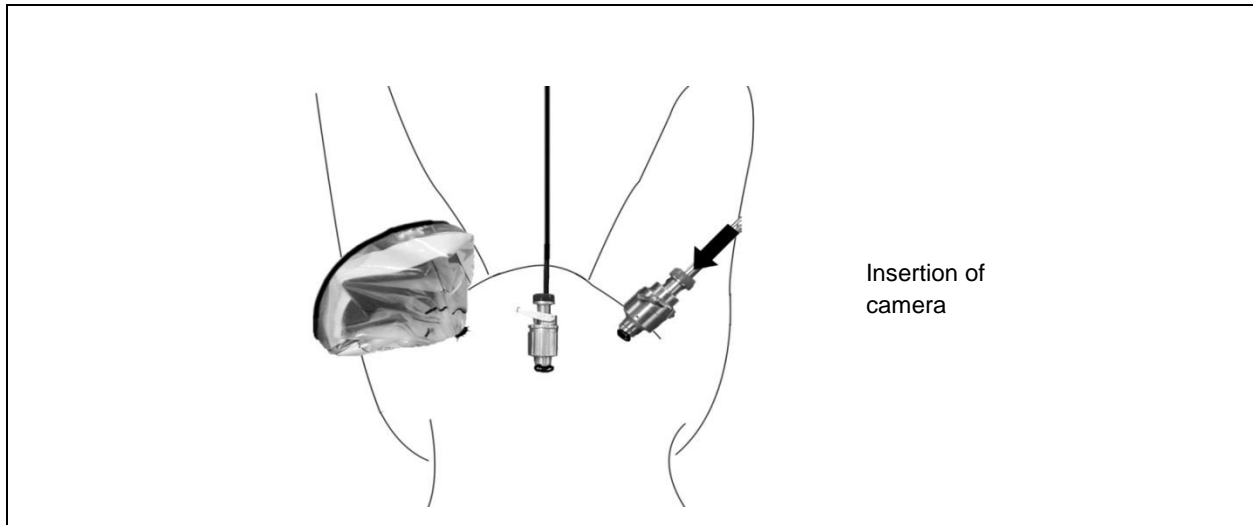


Figure 8: Insertion of camera through the side port

11. Insert the grasper into the abdominal cavity through the umbilical port.
12. Locate the tail end of the MorSafe® Morcellation Bag with the help of the distinctive Blue and Black checkered pattern provided on the tail.
13. With the help of the grasper that has been passed through the umbilical port, pull the tail end out through the umbilical port (Figure 9).
14. Remove the trocar from the umbilical port.

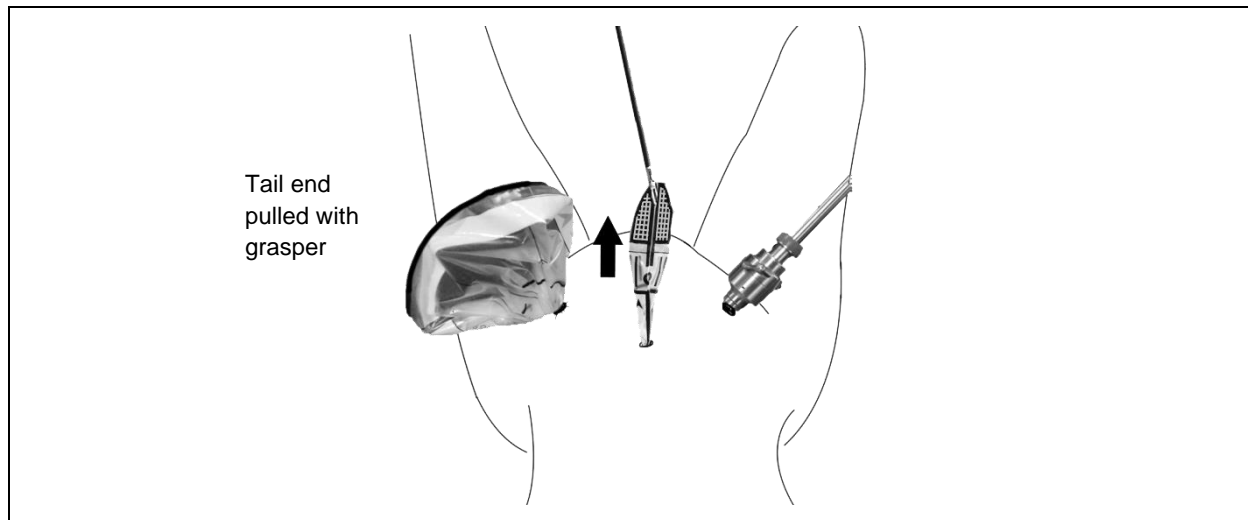


Figure 9: Pulling out trocar from the umbilical port

15. Make sure that the thick lining on the sealed edge of the bag is inside. This will help prevent twisting of the MorSafe® Tissue Morcellation Bag.
16. The Blue markings on the body of the bag should be kept on one side of the patient to avoid twisting of the bag.

17. Pass a blunt tip trocar through the hole present on the tail end of the Morcellation Bag and insufflate the abdomen (Figure 10). While passing the trocar, care should be taken to see that the trocar does not puncture the MorSafe® Tissue Morcellation Bag.
18. Pass a camera through this trocar and insufflate the MorSafe® Tissue Morcellation Bag.

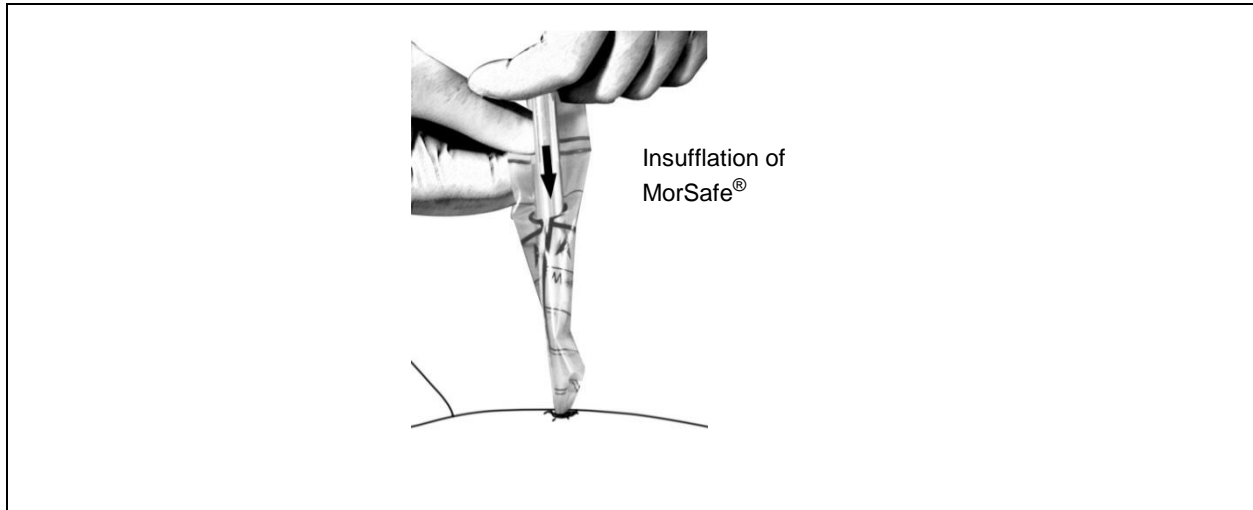


Figure 10: Passing a trocar from the tail end of the MorSafe® Tissue Morcellation Bag and Insufflation

19. Visualize the tissue inside the MorSafe® Tissue Morcellation Bag.
20. Insert a morcellator through the large opening of the MorSafe® Tissue Morcellation Bag (Figure 11). Exercise caution while passing the morcellator. Care should be taken to ensure that cutter blades of the morcellator are not in exposed position.
21. Now pass a grasper through the morcellator to hold the tissue and carry out morcellation.

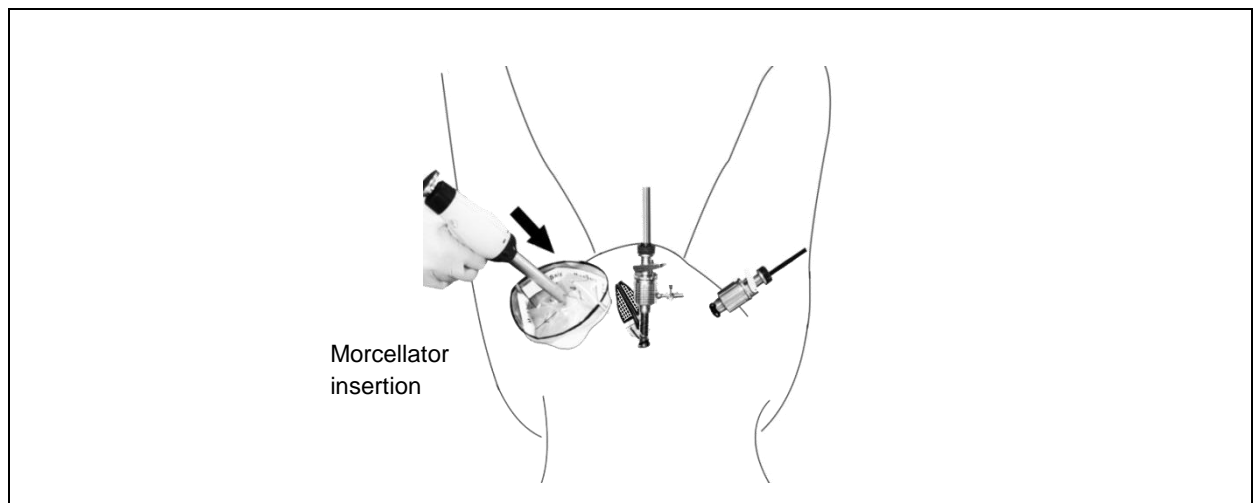


Figure 11: Inserting a morcellator through the big opening of the MorSafe® Tissue Morcellation Bag

22. After the tissue is sufficiently morcellated to enable the bag to be pulled out along with its content without much resistance through the incision made, remove the grasper from the morcellator. At this point, the size of the non-morcellated tissue may be compared with the size indicator marking

on the bag to determine if the tissue requires further morcellation or if the tissue can be pulled out with the bag without further morcellation.

23. Withdraw the morcellator from the abdominal cavity. Keep the cutter blades in unexposed position while removing the morcellator from the body.
24. Desufflate the MorSafe® Tissue Morcellation Bag.
25. Tie a secure knot at the tail end of the MorSafe® bag. This knot should be tied below the thick, horizontal line present at the tail end (Figure 12) so that the small opening on the tail end is isolated (made inaccessible) from the internal contents of the bag.



Figure 12: Knot tying at the tail end of the MorSafe® Tissue Morcellation Bag

26. Hold the large opening of the MorSafe® Tissue Morcellation Bag and pull it in the outward direction (Figure 13).

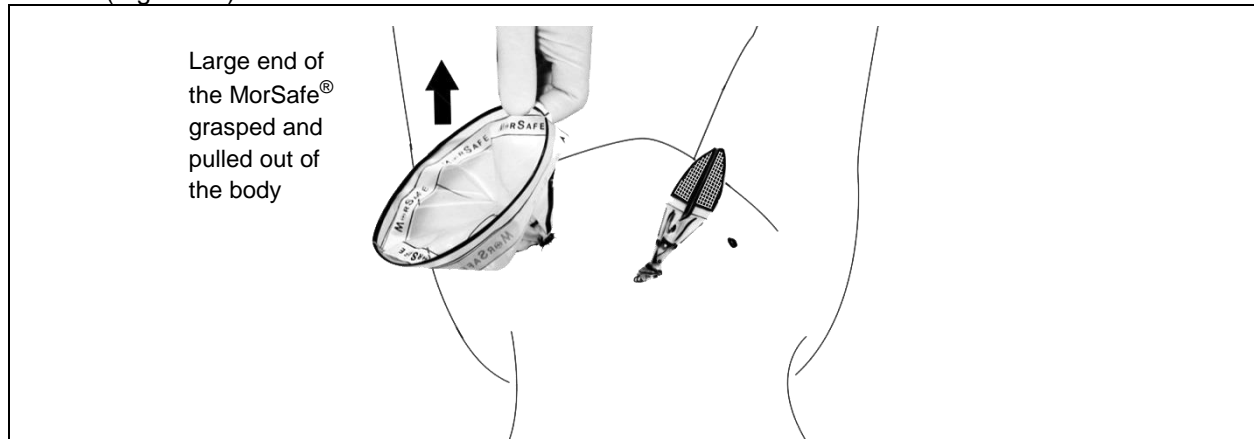


Figure 13: Pulling out MorSafe® Tissue Morcellation Bag from the body

27. During the procedure the surgical instruments which are inserted into the Morsafe® Tissue Morcellation Bag, might get stained with blood and tissue. Hence the surgical instruments should be thoroughly cleaned (or new sterile surgical instruments must be used) before re-inserting directly into the body orifice without Morsafe® Bag.