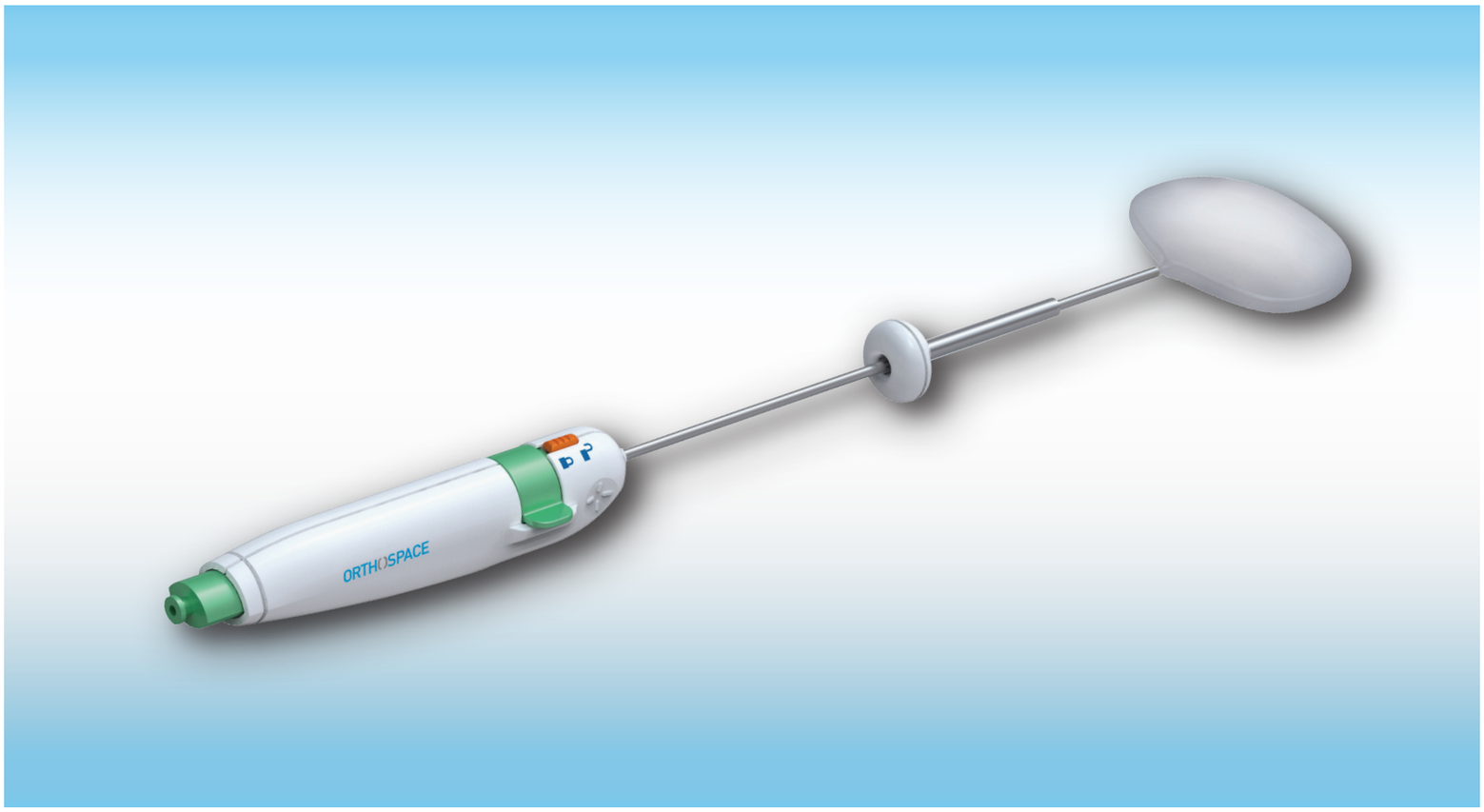
ORTHOSPACE

InSpace™

Surgical Procedure



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Check List

PRE OPERATIVE:

Verify with the surgeon:

- Patient age
- Pre-Operative ROM (passive & active)
- History of previous interventions in the treated shoulder
- Tear type (size and Goutallier classification)
- Presence of OA (by MRI, CT, US or X-ray)
- Prophylactic antibiotics protocol routinely used for implants

DIAGNOSTIC ARTHROSCOPY:

- Is the Supraspinatus repairable?
- What is the status of the Biceps tendon, and the Subscapularis?
- Verify actual OA grade, tear size and shape
- To allow proper deployment, ensure sufficient space (especially above the remaining stump of SSP)
- Note that the Coraco-acromion ligament is preserved
- Acromioplasty is not mandatory, and might be performed as per surgeon discretion

IMPLANTATION:

- Ensure 100cc of warm sterile Saline (If there is no option for warm Saline - room temperature will be sufficient) and a 50/60cc luer lock syringe with extension tube connected to a 3 way valve are available
- In order to select appropriate spacer size - instruct the surgeon to measure the distance (lateral to medial) and select the size according to the IFU/surgical technique brochure
- Open the non-sterile foil bag. Instruct the circulating nurse to confirm that the humidity indicator presents the appropriate colors as indicated in the IFU
- Entry portal might require enlargement
- In order to avoid premature detachment or sealing of the device, surgeon should be instructed to hold the green button over the protecting sheath, and avoid manipulating the protecting sheath during device insertion
- Instruct the surgeon to verify that the protecting sheath is located medially over the Glenoid rim or the SSP stump. Latterly, the laser mark should be clearly visualized, above the Greater Tubercle
- Once the protecting tube is retracted, no additional manipulation in device positioning can be made
- Following inflation of the device according to the table in the IFU/surgical technique brochure, ensure optimal volume for spacer stability by closing the 3-way valve, perform mild ROM and verify stability
- Once optimal volume and position has been obtained, the device should be sealed. It is recommended to hold the handle steadily using both hands; slide forward the red safety button; and rotate the green knob to the right

END OF PROCEDURE:

- Following spacer seal and introducer withdrawal, verify that the spacer is located properly and stable during passive range of motion
- The location can also be monitored by using arthroscopic lateral view, which provides good presentation of spacer position and stability during ROM maneuvers
- If there is a doubt regarding spacer position - spacer removal and replacement can be considered
- Discuss with the surgeon the rehabilitation process