SURGERY MANUAL

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Disclaimer

Disclaimer: The START:REACTS Study is being conducted in compliance with current regulations, guidelines, and legislation which serve to ensure the well-being of its participants and integrity of the data. To ascertain compliance from the research sites involved in this research we request readers of this manual to have awareness of the GCP principles listed below:

Good Clinical Practice (GCP) - 13 Principles

GCP is an internationally agreed **ethical and scientific quality standard** for designing, conducting, recording and reporting trials that involve the participation of **human subjects**.

Working to GCP principles provides assurance that the **rights, safety and well-being** of trial subjects are protected, we are working ethically and in accordance with the principles that have their origin in the **Declaration of Helsinki**, and that the clinical trial **data is credible.**

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s).
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.
4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

START:REACTS Surgery Protocol

Prior to the procedure, please confirm that the participant has been appropriately consented, registered for the study and that baseline data has been taken.

It is recommended that before performing this procedure, you should check the availability of the following with your theatre staff:

- An appropriate selection of sizes of the InSpace balloon.
- Warmed Saline (up to 40 degrees - 100ml bag).
- 50ml Leur Lock Syringe.
- Extension tubes with 3-way valve.
- Measurement Probe with 1cm increments (up to 7cm minimum). If you do not have a calibrated probe, an ACL depth gauge is another alternative option. If neither are available then a clip can be used on a standard probe to establish a measurement (as demonstrated on the START surgical video).

Patient positioning and choice of anaesthetic technique will be at the discretion of the surgical & anaesthetic teams.

Operative procedure and recommendations (for complete InSpace handling and instruction for use please refer to the package insert available at each device):

1) The choice of portals will be at the discretion of the surgeon, but the position of the portals must be such as to allow passage of the balloon (regardless of which group the patient is allocated to). The lateral portal should be 1-1.5cm to allow potential passage of the balloon, or to maintain blinding.

2) A diagnostic gleno-humeral arthroscopy will be performed initially. This will be to assess the shoulder joint and to confirm the patient meets the eligibility criteria.

>>**Specifically check** at this stage:

a. Presence of <u>advanced</u> gleno-humeral OA
b. Active or latent infection or signs of tissue necrosis in the implantation area.
a. Unrelated symptomatic shoulder disorder that would interfere with strength measurement or rehabilitation
b. Subscapularis tear (more than the superior 1cm)*

*If there is an upper border tear of subscapularis of less than 1cm, this can be repaired or not at the surgeons preference. IF it is repaired, please add this to the pre-prepared **open operation note** and **add any restrictions for rehabilitation** that might need to be applied. **Do any repair before the patient is randomised**, the same treatment **MUST** be applied to both arms.

3) Tenotomy of the long head of biceps, if it is still intact. A tenodesis will ***not*** be performed.

4) Perform a bursectomy

>>**Specifically check** at this stage:

Is the cuff **repairable**? If YES, proceed to repair and do not randomise. If NO, the participant can be randomised at this stage.

5) Determine whether the tear size is <3cm (medium) or large/massive (≥3cm), tell the nurse/research staff **"There is a Large/Massive (more than 3cm) OR Small/Medium (less than 3cm) tear"** and **"I have confirmed eligibility, please randomise the patient"**. The member of staff will use the online web-system (https://ctu.warwick.ac.uk/StartReactsOpNote) or will use the back-up telephone system (add phone number).

   Measure the AP and ML size of the tear (this can be approximate) for the post-operative note.

   Continue with the operation as though you will be inserting the balloon.

6) Clear the space for a potential balloon
   a. Expose the superior aspect of the glenoid (to give a point of reference for the measurement)
   b. Clear tissue in the subacromial space 1 to 2cm medial to the edge of the glenoid to ensure the balloon will 'sit' in the correct position. (confirm with measuring device eg graduated probe/hook)

7) Debride the edges of the cuff tear as necessary for visualisation and access

8) Perform a **limited decompression** of the subacromial space. **Keep the coraco-acromial ligament intact** (that is, in continuity – a few fibres may need to be taken to do a limited acromioplasty but it is important to maintain the integrity of the ligament)**.**

   A limited bony acromioplasty (for example, removing a spur on the antero-lateral margin, or smoothing a prominent bony protuberance) is acceptable provided the CA ligament is not divided.

   Tuberoplasty can be performed at this stage if this is part of the surgeons normal practice, but is not routinely recommended.

9) The AC Joint can be excised according to the surgeon's normal clinical approach. Only perform this if there is tenderness specifically at the ACJ, positive provocative signs ***AND*** radiological evidence of ACJ OA.

10) Reveal the study allocation to the surgeon and theatre team (if the patient is awake, do this on a piece of paper shown to the surgeon and the team, do not announce it so that the patient could hear)

11) IF RANDOMISED TO ARTHROSCOPIC DEBRIDEMENT:

Take an arthroscopic photograph from both posterior and lateral portals, to demonstrate the debridement, which should show the cuff, the acromion and the CA ligament. Please print off a second set of photos for the trial team.

Close the wounds and use dressings and bandages according to your standard technique, *[continue to step 19 – blinded operation note]*

12) IF RANDOMISED TO ARTHROSCOPIC DEBRIDEMENT AND THE INSPACE BALLOON:

Take an arthroscopic photograph from both posterior and lateral portals, to demonstrate the debridement, which should show the cuff, the acromion and the CA ligament.

Follow the remaining steps to insert the balloon:

13) Use the lateral port to measure the distance from the lateral border of the greater tuberosity to approximately 1cm medial to the glenoid apex (use standard measuring probe).

Then select the InSpace device size based on recommended Device Size and Volume Guide below (Table 1)

ML measurement of the acromion

Table 1: device Size and Volume Guide

Medial-Lateral (ML) measurement (mm)	Device Size	Max volume to spread the device (ml)	Recommended final inflation volume (ml)
< 40	Small	15-17	9-11
41-50	Medium	22-24	14-16
>51	Large	40	23-25

14) Prepare the inflating system in advance. Fill syringe with saline heated to ~40 degrees Celsius, and remove any air bubbles (in syringe, extension tube and valve).
15) Introduce the InSpace™ delivery system through a true lateral port. The Balloon should be advanced over the glenoid rim and ~1cm over the Rotator Cuff tendon stump.

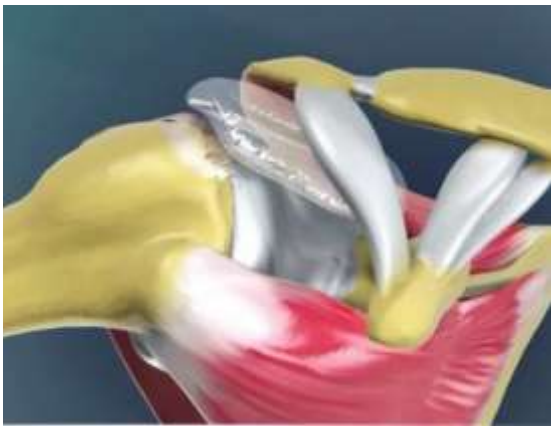
    During insertion: Do not use excessive force on the device to avoid damage or breakage during use.
    Avoid unintended contact with other surgical instruments during use to prevent damage to the device.

16) After final positioning of the delivery system pull back the protecting sheath and expose the balloon. Re-verify balloon position in the subacromial space.

17) Connect the extension tube to the rear side of the delivery system (Luer-lock connector), connect the syringe with the preheated saline to the connector. Inflate the Balloon to full volume (check table above). Keep the valve open and let saline flow back into the syringe by gently moving the shoulder in passive motions (the deflation can be done manually). Do not over or under inflate the balloon to avoid increasing subacromial pressure (see recommended inflation volumes according to Balloon size in the table above). When satisfied with balloon position and volume, seal the Balloon **verifying positioning and stability of the implanted balloon**. Perform gentle movements of the patient's arm to verify correct positioning and stability of the balloon, prior to sealing and detachment

18) For sealing and detachment of the Balloon push the red safety button forward and turn the green knob clockwise till full detachment. Remove the delivery system and go through full passive ROM. Verify that the Balloon is stable in situ, and cannot be subluxed or dislocated.

Note: In the event that any difficulty is encountered with inflation, Sealing or proper placement of the InSpace™ balloon, it can be either deflated, removed and replaced with another InSpace™ balloon or (less recommended) left *in-situ* deflated.
Note: Do not use any solutions for inflation of InSpace™ Implant other than sterile physiological solution (i.e. sterile saline). Inspect the InSpace™ Deployer parts after use to ensure they have not been damaged.



19) Perform movements with the patient's arm to check for full range of motion, making sure there is no restriction of arm movement. Verify the Implant is correctly positioned, that it is stable, and cannot be dislodged by arm movement.

    Take an arthroscopic photograph from the posterior portal just before balloon inflation to demonstrate accurate balloon position relative to the edge of the acromion.

20) Suture the incisions and use dressings and bandages according to your standard technique

The operation is complete

21) Use the **pre-prepared BLINDED operation notes** for the hospital record – these are available electronically or in print. Add any changes to the rehab programme you would like (for example, if you have repaired subscapularis)

22) Complete the **blinded part of your operation note online** using our operation note module (https://ctu.warwick.ac.uk/StartReactsOpNote). This will be very short and no slower than using a hospital system. It counts as a clinical record for the end of the procedure, and will be entered into the notes at the end of the study (in 2 years).

    A paper version of the operation data form (where you can record your normal op note information) will also be available, but will need to be copied to the online

system by a member of staff as soon as possible to allow access in case of an emergency.

THANK YOU FOR TAKING PART IN THIS STUDY