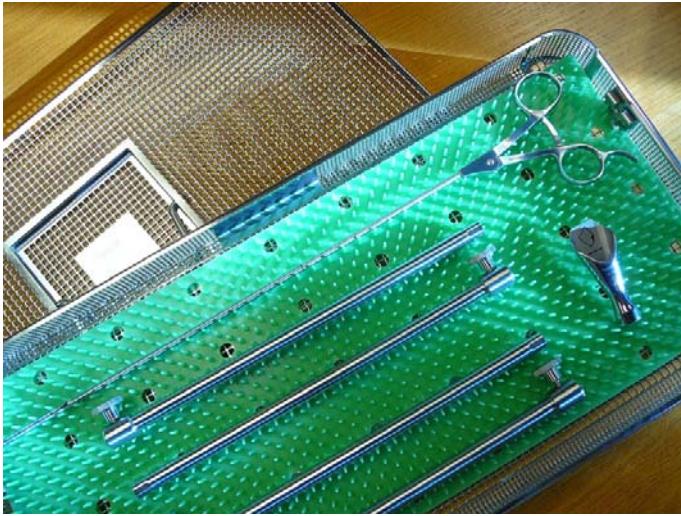


Preparation of TissuePatchThoracic using VATS instrument assembly for presentation to the operating surgeon

Instructions for scrub nurse



This is a simple procedure that enables a single operator to load a TissuePatchThoracic device directly from its packaging into a dedicated introducing tube for presentation to the operating surgeon with minimal handling. The procedure can be performed by one person but requires a little practice, care and planning to achieve the best results. TissuePatchThoracic is a thin film that is easily damaged, so care must be taken at all times during this operation.

Kit contents (ref. TIS-05):

- One fluted loader (ref. TIS-01)
- Four introducing tubes (ref. TIS-02), each with a locking screw which must be removed for cleaning and assembled for use.
- One grasper (ref. TIS-03)
- One instrument tray (ref. TIS-04)

Step 1: Assembling the instruments

- Ensure all components are dry (especially the open mouths of the loader and introducing tube because moisture in these components will result in failure to load or dispense the patch).
- Carefully but firmly attach the loader to the front of the introducing tube ensuring that the laser marking is uppermost on both components; ensure components are fully engaged.



- Insert the grasper through the tube until the jaws are fully outside the loading funnel. Turn the locking screw to secure the grasper in the tube assembly.
- Open the grasper jaws slightly in readiness for loading the patch. Set the assembly aside and now prepare the patch.



Insert grasper with handle down



Lock grasper in introducing tube



Open grasper jaws

Step 2: Preparing the patch for loading into the introducing tube



- Carefully open the packaging and peel to expose approximately half of the length of the patch as this length must be engaged in the grasper jaw.
- Hold the packaging, including patch, in one hand in an orientation that presents the product to the open grasper jaw whilst supporting both components.
- With the grasper jaw slightly open at all times, advance it until final location on the patch is confirmed. When satisfied that that the grasper jaw is central and the patch does not extend beyond the laser mark in the loader funnel (or on the grasper), carefully close the grasper jaw firmly and fully.

Step 3: Pulling the patch into the introducing tube

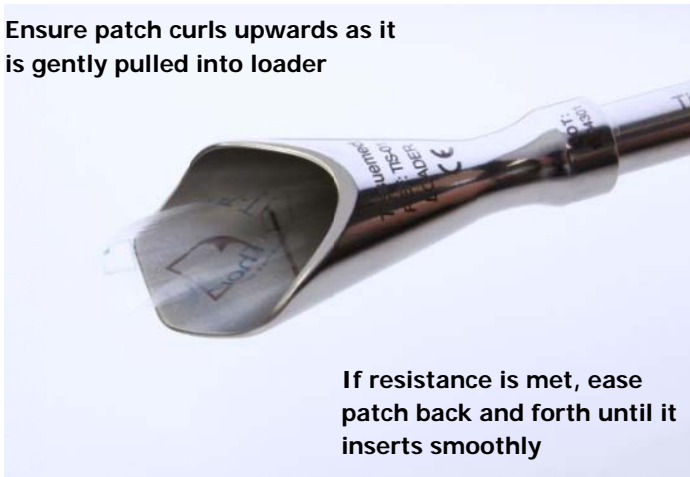
Loosen locking screw with grasper handle pointing downwards



Gently start to withdraw the grasper from the introducing tube

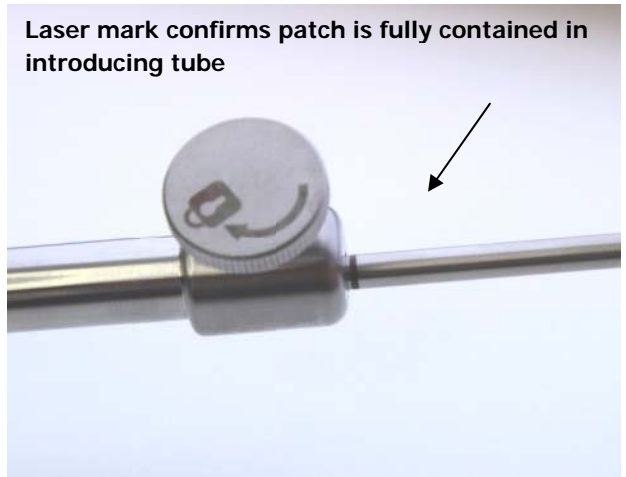


Ensure patch curls upwards as it is gently pulled into loader



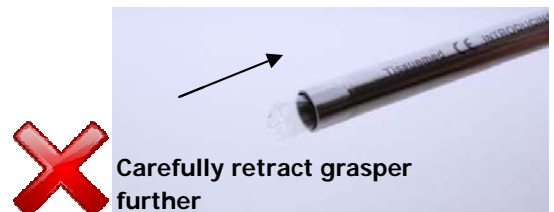
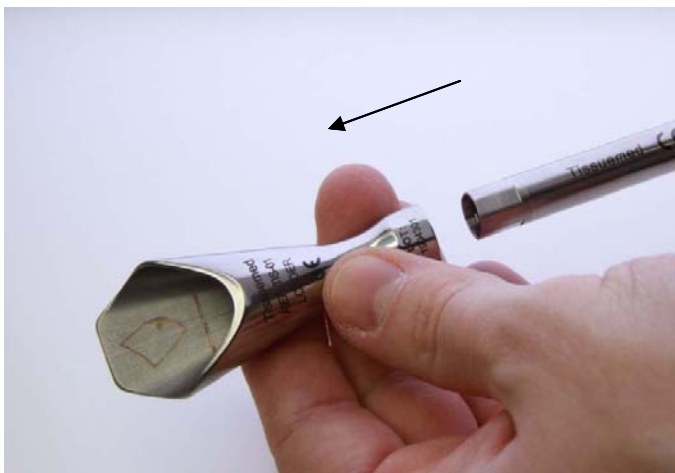
If resistance is met, ease patch back and forth until it inserts smoothly

Laser mark confirms patch is fully contained in introducing tube



Caution: Do not pull the grasper back beyond the laser mark point as this will damage the patch as it is forced into the narrow section of the tube. If the patch has been damaged, it is advisable to replace it.

- Carefully remove the loader by pulling it off the front on the introducing tube and visually confirm that the patch is enclosed in the mouth of the tube.



- Turn the locking screw to secure the grasper inside the introducing tube.

The assembly is now ready to be passed to the operating surgeon.

Preparation of TissuePatchThoracic using VATS instrument assembly for introduction to the operative site

Instructions for surgeon

Receiving the instrument assembly

The surgeon will be passed a fully assembled instrument including a preloaded 8cm x 3cm patch. The assembly should be received with the components locked together and the patch locked in the grasper mouth. A laser mark should be visible on the grasper shaft where it interfaces with the back of the introducing tube. Inspection of the mouth of the introducing tube should confirm the presence of a patch fully protected by the tube. The assembly has an outer working diameter of 11mm and can be inserted either through the chest wall or through an appropriately sized operating cannula. The patch will be delivered in a longitudinal orientation in order that it can be aligned with the long axis of staple lines.

Insertion into the chest cavity

- Holding the body of the Introducing Tube, guide it through the chest wall channel most appropriate to the orientation of the target tissue.
- Advance the tube until its distal opening is close to the distal aspect of the target tissue.

Delivering the patch to the tissue surface

- Support the Introducing Tube plus Grasper in one hand while loosening the locking screw sufficiently to permit the Grasper to move within the tube.
- Advance the Grasper and visualise on-screen the tip of the patch appearing (A). The patch will remain curled, but remember that the centre line of the grasper will indicate the centre of the patch. Gently place the patch tip on the tissue surface just distal to the target area (B).



- Withdraw the introducing tube far enough for the entire grasping jaw to be in view (C). It may be helpful to re-lock the introducing tube to ensure it does not slide back down over the grasper. Gently open the jaw enough to release the patch (C & D). *Note: Using a dry peanut through a secondary portal to secure the distal portion of the patch will ensure it remains in situ during this stage of the operation.*
- Once the patch is in approximate position, the grasper plus assembly can be removed as a single unit. Pass assembly back to scrub nurse for loading of additional patch as required, remembering to wipe the grasper jaws dry and use a clean dry introducing tube for subsequent patches.
- Peanuts can be used to manipulate the patch more firmly into desired location along the staple line, gently smoothing it over the raised staple line and onto adjacent wound edges.

Caution: Once final desired position has been achieved, continued manipulation should be avoided as this may disturb the contact between patch and tissue surface.

NOT FOR EXPORT TO U.S.A.

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