

c. Withdraw the grasper and re-insert* the cannula spindle in the tube holder.
***WARNING: required step to ensure exact trajectory of the Resadisc® electrode.**

d. Check positioning via fluoroscopy and introduce Resadisc® until correct alignment between distal marker and trocar.



e. Activate the generator (previously set to 25W) by footswitch, advancing Resadisc® to the maximum depth permitted by the safety system within 4 seconds.



WARNING: The tip of the Resadisc® electrode must not come into contact with the anterior annulus.

f. Repeat points d and e 4 times.

3 REMOVAL AND WARNINGS

At the end of treatment, extract the Resadisc® electrode and all related components from the patient.

WARNING: Do not extract the Resadisc® electrode whilst active.

- 1 Carefully examine the anteroposterior and lateral projections under fluoroscopy.
- 2 Confirm the correct positioning of the cannula and Resadisc® electrode inside the target tissue.

For a more detailed list of warnings and precautions, refer to the Resadisc® disc decompression kit Instructions for Use.

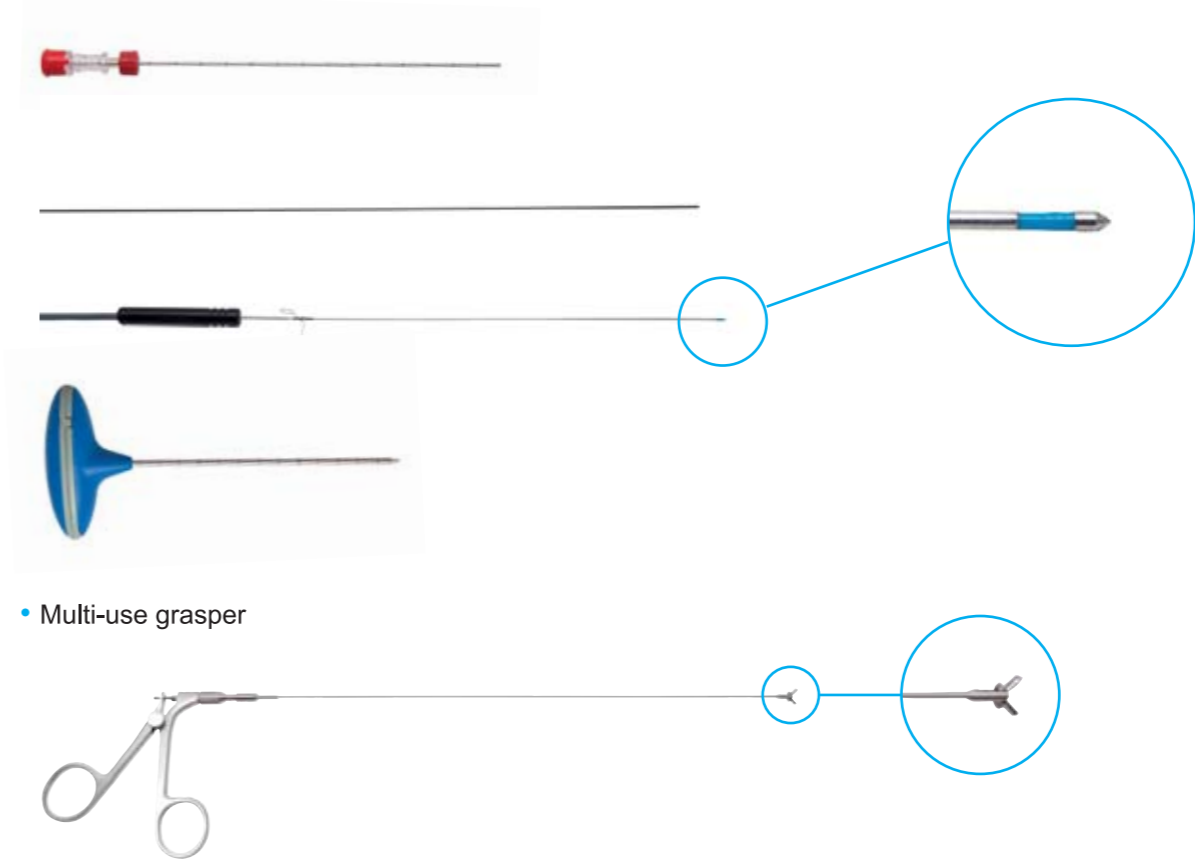
INSTRUCTIONS FOR USE

- Disc protrusions
- Contained hernias
- Radicular pain caused by nerve compression

The disc decompression procedure with QMR^{®1} technology should only be performed by qualified medical personnel.

EQUIPMENT

- C-arm fluoroscope with image intensifier
- Resablator Smart and/or Resablator50 generator
- Resadisc® kit



- Multi-use grasper

PREPARATION

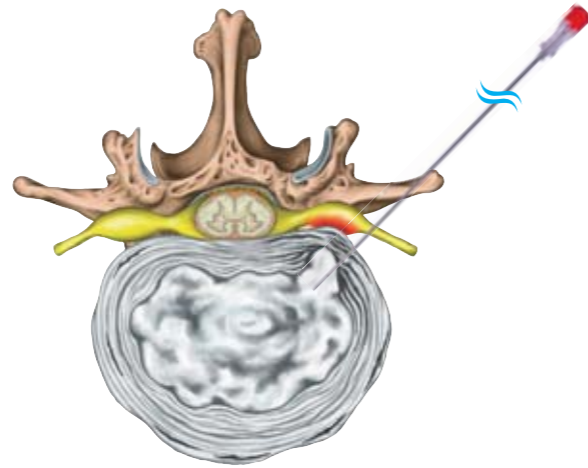
Surgery can be performed under local anaesthetic.

- Connect the Resablator generator power cable to the power supply.
- Connect the footswitch to the generator.
- Place the Resadisc® kit components on a sterile field.
- Connect the Resadisc® bipolar electrode to the generator.
- Set power level to 25W.
- Prepare the patient by following the normal pre-operative procedures.

DISC DECOMPRESSION

1 PERCUTANEOUS ACCESS

a. Use the fluoroscopic imaging technique and insert the 17G introducer needle through the Kambin's triangle and past the annulus/nucleus juncture.

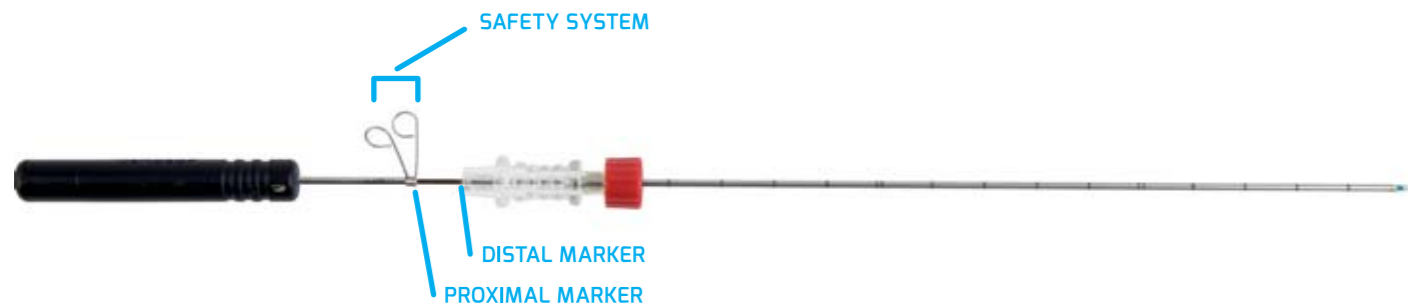


b. Remove the stylet and insert Resadisc[®] into the introducer needle until correct alignment between the distal marker of the electrode and the needle connector.

There is a safety system on the shaft of the device capable of modulating the depth of decompression.

Check by imaging that the tip of the Resadisc[®] electrode is inside the nucleus and sufficiently far from the vertebral plates throughout the area of operation.

If necessary, the extension of treatment can be reduced by repositioning the safety system within the marker itself.

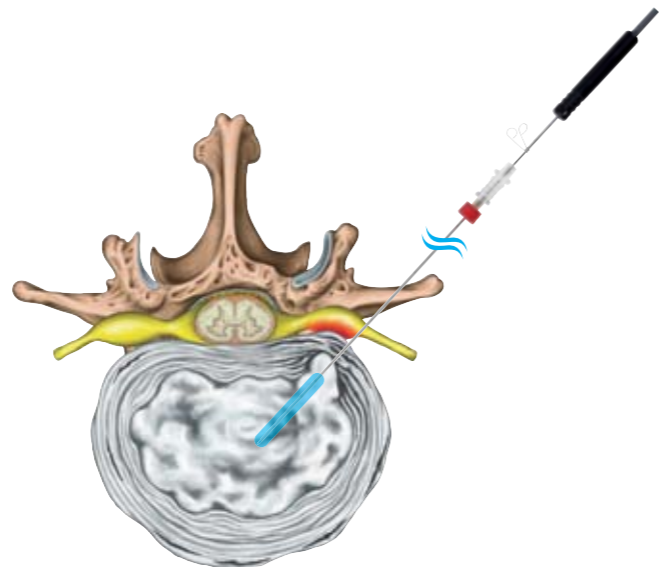


2 DECOMPRESSION

a. Activate the generator (previously set to 25W) by footswitch, advancing Resadisc[®] to its maximum permitted depth within 4 seconds.

b. Retract the electrode to the distal marker.

c. Repeat points a and b up to 4 times.



SURGICAL MICRODISCECTOMY

1 MINI-OPEN ACCESS

a. Use the fluoroscopic imaging technique and insert the 17G introducer needle through the Kambin's triangle, passing the annulus/nucleus juncture.

b. Remove the spindle and insert the guidewire.



c. Extract the needle leaving the guidewire in place and make an incision (approximately 1cm).

d. Run the 11G trocar cannula along the guidewire until it reaches the nucleus pulposus.



e. Extract the guidewire and stylet from the tube holder, taking care to place them on the sterile field.



2 MICRODISCECTOMY

a. Introduce the grasper through the tube holder.

b. Remove the desired amount of disc tissue, acting on the appropriate handle.

