



T O R A X
M E D I C A L I N C

LINX[®] Reflux Management System Device Dilation

Intervention - Dilation

The following are recommended steps if balloon dilation of the LINX[®] Reflux Management System is indicated.

Please contact your Torax representative for technical support before performing any interventional procedure on the LINX device.

Intervention - Dilation

Indication	Balloon dilation of the LINX device is generally indicated for patients presenting with unresolved dysphagia/odynophagia (typically greater than 6 weeks post-implant)
Facilities	C-arm or radiology suite
Materials	<ul style="list-style-type: none">• Endoscope• Insufflator (with 50/50 contrast and saline cocktail)• Esophageal dilation balloon (15mm)

Recommended Steps in Balloon Dilation

1. *Sedate the patient for endoscopy in the radiology or endo suite.*
2. *Position the patient/x-ray in a manner that provides good oblique visualization of the individual beads of the device.*
3. *Identify the number of beads in the device and determine expanded diameter (reference the following slides for schematic showing the expanded diameter of the corresponding implant).*
4. *Introduce the endoscope to confirm that the health of the esophagus, GEJ and stomach are suitable for dilation (this is a good opportunity to pass the endoscope through the device to assess the level of resistance).*
5. *If assessment of esophagus indicates health is acceptable, proceed to next steps. If unacceptable, do not proceed with dilation.*

Recommended Steps in Balloon Dilation

6. *Introduce and center a dilation balloon with an expanded diameter no bigger than 15mm on the device.*

Note: *It can be helpful to use a 50/50 saline/contrast media mix that will make the balloon semi-opaque and allow its profile to be observed without complete obstruction of the beads behind the balloon.*

7. *Expand the balloon in a step-wise fashion with careful attention directed to the number of beads that have opened.*

Note: *The magnets are radio-opaque, not the bead casing, so bead separation is determined by the relative change in the distance between the observed magnets.*

8. *Stop at any time to assess the GEJ during expansion. Keep in mind that the balloon is displacing the esophagus and the device.*

Recommended Steps in Balloon Dilation

9. Continue expanding the balloon in a step-wise fashion; stopping at nominal pressure or when a minimum of three beads remain closed.

Note: DO NOT expand the balloon to the point that all beads are open, as this may damage tissue and/or the device.

10. Remove the dilation balloon and examine the esophagus, GEJ and stomach again with the endoscope, using this opportunity to confirm that no damage has taken place.

11. Liquid and solid barium esophagrams can be performed at clinician discretion to assess bolus transit.

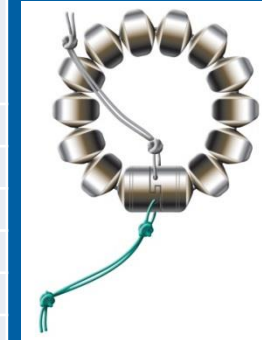
12. Discharge the patient per clinician guidance.

13. The patient should resume a normal diet as tolerated to maintain bead actuation.

LINX Implant Dimensions

LINX - Clasp

Device Size	Closed Diameter (mm)	Open Diameter (mm)	Open Diameter with tissue (mm)	Beads opened with a 15 mm Balloon fully distended
12-Bead	12.3	22.5	18.8	9
13-Bead	13.6	25.3	21.3	9
14-Bead	14.9	27.8	23.5	8
15-Bead	16.2	30.4	25.7	8
16-Bead	17.5	32.9	27.9	7
17-Bead	18.7	35.8	30.1	7



LINX-Suture

Device Size	Closed Diameter (mm)	Open Diameter (mm)
12-Bead	12.3	22.5
13-Bead	13.6	25.4
14-Bead	14.9	28.5
15-Bead	16.2	31.6
16-Bead	17.5	34.8
17-Bead	18.9	37.3

