Designed to prevent reherniation

Published Clinical Evidence Overview

BARRICAID®

These articles contain off-label use information. Please use medical discretion when reviewing these articles.

Barricaid is approved for the following indications for use:
Reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

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Full financial disclosures can be found in the respective manuscripts.

Levels of Evidence for Published Papers of the Barricaid device for annulus fibrosus closure

Study	Ref.	Level	Notes
LEVEL I EVIDENCE			
Meta-analysis of randomized trials	1,83,85,86	Ia	
554-patient randomized trial	2-3, 5-12, 14-17, 24, 77	Ib	
60-patient randomized trial	13	Ib	
LEVEL II EVIDENCE			
Network meta-analysis	20	IIb	Systematic review of Level IIIb evidence; upgraded since a SR is rated higher than the underlying evidence.
Meta-analysis of controlled studies	21	IIb	Systematic review of Level IIIb evidence; upgraded since a SR is rated higher than the underlying evidence.
Krutko Cohort Study	18	IIb	
Superiority Claims: Systematic Review	19	IIb	
LEVEL III EVIDENCE			
ISASS Policy Guideline	22	IIIb	
Systematic review of Barricaid results	23	IIIb	Systematic review of Level IV evidence; upgraded since a SR is rated higher than the underlying evidence.
Cohort A controlled study	26,28	IIIb	
Cohort B controlled study	25	IIIb	
Combined Cohort A & B controlled study	27	IIIb	
Murphy Annular Closure Review	4	IIIb	
LEVEL IV EVIDENCE			
Cohort A case series	38	IV	
Combined cohort A & B case series	36,37	IV	
Ardeshiri case series	30,31	IV	
Kursumovic case series	32,35	IV	
Martens case series	33	IV	
Sanginov case series	34	IV	
Kienzler RCT + case series	29	IV	
US Cohort case series	82	IV	
Kurzbuch case series	81	IV	
LEVEL V EVIDENCE			
Gautschi case report	48	V	
Hahn case report	49	V	
Krutko case report	47	V	
Lange case report	42	V	
McClure case report	84	V	
Barth letter to editor	43	V	
Bouma letter to editor	50	V	
Grasso letter to editor	41	V	
Izci letter to editor	51	V	

Klassen letter to editor	46	V	
Lange letter to editor	45	V	
Shiban letter to editor	44	V	
Burkhardt case report	39	V	
Castro editorial	40	V	
Kienzler letter to editor	79	V	
Kurzbuch letter to editor	80	V	
UNGRADED EVIDENCE			
Ammerman WC reoperation study	52		
Ament health economics study (a)	53		
Ament health economics study (b)	56		
Bostelmann health economics study	54		
Klassen health economics study	58		
Parker health economics study	61		
Thaci health economics study	57		
554-patient randomized trial protocol paper	59		
US case series protocol paper	55		
Bostelmann preclinical paper	60		
Wilke preclinical paper	62		
Annular Closure Device Design Considerations	78		
DEFINING THE CLINICAL NEED			
Discectomy outcomes are not perfect	63-75		

Grading scale: Oxford Centre for Evidence-Based Medicine Levels of Evidence

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