

CLINICAL BENEFITS

- Rapid inflation and deflation
- Complete deflation allows for ease of removal

ECONOMIC BENEFITS

- Durable catheter minimizes need for multiple balloons in a single procedure
- 5 stage balloon expands dilation range with one balloon

QUICK FACTS

- Box quantity: 1
- Single use
- Not made with natural rubber latex or DEHP
- Sterility: ETO
- Shelf life: 3 years
- Elation FDA Clearance:
 - Fixed Wire:
 - FDA Class I Exempt Medical device
 - Regulation number: 876.5365
 - Wire Guided:
 - FDA Class II medical device
 - 510(k) number: K151925
 - <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K151925>

CODING*

Healthcare Common Procedure Code(s) (HCPCS)

- C1726 Catheter, balloon dilatation, non-vascular

Common Procedure Terminology (CPT) Code(s)

- 43195 - Esophagoscopy, rigid, transoral; with balloon dilation (less than 30 mm diameter)
- 43214 - Esophagoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
- 43220 - Esophagoscopy, flexible, transoral; with transendoscopic balloon dilation (less than 30 mm diameter)
- 43233 - Esophagogastroduodenoscopy, flexible, transoral; with dilation of esophagus with balloon (30 mm diameter or larger) (includes fluoroscopic guidance, when performed)
- 43249 - Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
- 44381 - Ileoscopy, through stoma; with transendoscopic balloon dilation
- 44405 - Colonoscopy through stoma; with transendoscopic balloon dilation
- 45340 - Sigmoidoscopy, flexible; with transendoscopic balloon dilation
- 45386 - Colonoscopy, flexible; with transendoscopic balloon dilation
- 43277 - Endoscopic retrograde cholangiopancreatography (ERCP); with transendoscopic balloon dilation of biliary/pancreatic duct(s) or of ampulla (sphincteroplasty), including sphincterotomy, when performed, each duct

Balloon or Rigid

- 43196 - Esophagoscopy, rigid, transoral; with insertion of guide wire followed by dilation over guide wire
- 43213 - Esophagoscopy, flexible, transoral; with dilation of esophagus, by balloon or dilator, retrograde (includes fluoroscopic guidance, when performed)
- 43226 - Esophagoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) over guide wire
- 43245 - Esophagogastroduodenoscopy, flexible, transoral; with dilation of gastric/duodenal stricture(s) (eg, balloon, bougie)
- 43248 - Esophagogastroduodenoscopy, flexible, transoral; with insertion of guide wire followed by passage of dilator(s) through esophagus over guide wire
- 45303 - Proctosigmoidoscopy, rigid; with dilation (eg, balloon, guide wire, bougie)

International Classification of Disease (ICD) Codes:

- 0D71 Esophagus, Upper
- 0D72 Esophagus, Middle
- 0D73 Esophagus, Lower
- 0D74 Esophagogastric Junction
- 0D75 Esophagus
- 0D76 Stomach
- 0D77 Stomach, Pylorus
- 0D78 Small Intestine
- 0D79 Duodenum
- 0D7A Jejunum
- 0D7B Ileum
- 0D7C Ileocecal Valve
- 0D7E Large Intestine
- 0D7F Large Intestine, Right
- 0D7G Large Intestine, Left
- 0D7H Cecum
- 0D7K Ascending Colon
- 0D7L Transverse Colon
- 0D7M Descending Colon
- 0D7N Sigmoid Colon
- 0D7P Rectum
- 0D7Q Anus

Medicare Severity-Diagnosis Related Group (MS-DRG) Code(s)

- 369 Major esophageal disorders with cc
- 370 Major esophageal disorders without cc/mcc
- 371 Major gastrointestinal disorders and peritoneal infections with mcc
- 372 Major gastrointestinal disorders and peritoneal infections with cc

- 373 Major gastrointestinal disorders and peritoneal infections without cc/mcc
- 374 Digestive malignancy with mcc
- 375 Digestive malignancy with cc
- 376 Digestive malignancy without cc/mcc
- 388 G.i. Obstruction with mcc
- 389 G.i. Obstruction with cc
- 390 G.i. Obstruction without cc/mcc
- 391 Esophagitis, gastroenteritis and miscellaneous digestive disorders with mcc
- 392 Esophagitis, gastroenteritis and miscellaneous digestive disorders without mcc
- 393 Other digestive system diagnoses with mcc
- 394 Other digestive system diagnoses with cc
- 395 Other digestive system diagnoses without cc/mcc
- 444 Disorders of the biliary tract with mcc
- 445 Disorders of the biliary tract with cc
- 446 Disorders of the biliary tract without cc/mcc

United Nations Standard Products and Services Code (UNSPSC)

- 42294909 Endoscopic dilators or inflation devices

GLOBAL TRADE ITEM NUMBER (GTIN)

Elation - Fixed Wire

E6	00884450197776
E8	00884450197769
E10	00884450197783
E12	00884450197806
E15	00884450197813
E18	00884450197820
EX6	00884450383476
EX8	00884450383483
EX10	00884450383438
EX12	00884450383445
EX15	00884450383452
EX18	00884450383469

Elation - Wire Guided

EPB6	00884450258095
EPB8	00884450258101
EPB10	00884450258118
EPB12	00884450258125
EPB15	00884450258132
EB18	00884450258149
EPCB6	00884450258002
EPCB8	00884450258019
EPCB10	00884450258033
EPCB12	00884450258064
EPCB15	00884450258071
ECB18	00884450258088

CROSS REFERENCE

Merit Medical Endotek		Boston Scientific	
SKU	Device Description	SKU	Device Description
E6	3-Stage Esophageal Dilation Balloon 6-7-8 mm, 8 cm	M00558330	3-Stage Esophageal Dilation Balloon 6-7-8 mm, 8 cm
E8	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm	M00558340	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm
E10	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm	M00558350	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm
E12	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm	M00558360	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm
E15	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm	M00558370	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm
E18	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm	M00558380	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm
EX6	5-Stage Esophageal Dilation Balloon 5-6-7-8-9 mm, 8 cm	Not Offered	
EX8	5-Stage Esophageal Dilation Balloon 7-8-9-10-11 mm, 8 cm	Not Offered	
EX10	5-Stage Esophageal Dilation Balloon 9-10-11-12-13 mm, 8 cm	Not Offered	
EX12	5-Stage Esophageal Dilation Balloon 11-12-13.5-15-16 mm, 8 cm	Not Offered	
EX15	5-Stage Esophageal Dilation Balloon 14-15-16.5-18-19 mm, 8 cm	Not Offered	
EX18	5-Stage Esophageal Dilation Balloon 17-18-19-20-21 mm, 8 cm	Not Offered	
EPB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	M00558600	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm,
EPB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	M00558610	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm
EPB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	M00558620	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm
EPB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	M00558630	3-Stage Esophageal Dilation Balloon 9-7-8 mm, 5 cm
EPB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	M00558640	3-Stage Esophageal Dilation Balloon 9-7-8 mm, 5 cm
EB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	M00558650	3-Stage Esophageal Dilation Balloon 9-7-8 mm, 5 cm
EPCB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	M00558660	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm
EPCB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	M00558670	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm
EPCB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	M00558680	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm
EPCB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	M00558690	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm
EPCB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	M00558700	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm
ECB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	M00558710	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm

CROSS REFERENCE

Merit Medical Endotek		Cook Medical	
SKU	Device Description	SKU	Device Description
E6	3-Stage Esophageal Dilation Balloon 6-7-8 mm, 8 cm	Not Offered	
E8	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm	G31928	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm
E10	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm	G31925	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm
E12	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm	G31926	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm
E15	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm	G48732	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm
E18	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm	G31927	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm
EX6	5-Stage Esophageal Dilation Balloon 5-6-7-8-9 mm, 8 cm	Not Offered	
EX8	5-Stage Esophageal Dilation Balloon 7-8-9-10-11 mm, 8 cm	Not Offered	
EX10	5-Stage Esophageal Dilation Balloon 9-10-11-12-13 mm, 8 cm	Not Offered	
EX12	5-Stage Esophageal Dilation Balloon 11-12-13.5-15-16 mm, 8 cm	Not Offered	
EX15	5-Stage Esophageal Dilation Balloon 14-15-16.5-18-19 mm, 8 cm	Not Offered	
EX18	5-Stage Esophageal Dilation Balloon 17-18-19-20-21 mm, 8 cm	Not Offered	
EPB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	Not Offered	
EPB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	Not Offered	
EPB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	Not Offered	
EPB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	Not Offered	
EPB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	Not Offered	
EB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	Not Offered	
EPCB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	Not Offered	
EPCB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	G51799	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm
EPCB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	G51795	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm
EPCB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	G51796	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm
EPCB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	G51797	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm
ECB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	G51798	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm

Merit Medical Endotek		Micro Tech	
SKU	Device Description	SKU	Device Description
E6	3-Stage Esophageal Dilation Balloon 6-7-8 mm, 8 cm	MB24015	3-Stage Esophageal Dilation Balloon 6-7-8 mm, 8 cm
E8	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm	MB24025	3-Stage Esophageal Dilation Balloon 8-9-10 mm, 8 cm
E10	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm	MB24035	3-Stage Esophageal Dilation Balloon 10-11-12 mm, 8 cm
E12	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm	MB24045	3-Stage Esophageal Dilation Balloon 12-13.5-15 mm, 8 cm
E15	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm	MB24055	3-Stage Esophageal Dilation Balloon 15-16.5-18 mm, 8 cm
E18	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm	MB24065	3-Stage Esophageal Dilation Balloon 18-19-20 mm, 8 cm
EX6	5-Stage Esophageal Dilation Balloon 5-6-7-8-9 mm, 8 cm	Not Offered	
EX8	5-Stage Esophageal Dilation Balloon 7-8-9-10-11 mm, 8 cm	Not Offered	
EX10	5-Stage Esophageal Dilation Balloon 9-10-11-12-13 mm, 8 cm	Not Offered	
EX12	5-Stage Esophageal Dilation Balloon 11-12-13.5-15-16 mm, 8 cm	Not Offered	
EX15	5-Stage Esophageal Dilation Balloon 14-15-16.5-18-19 mm, 8 cm	Not Offered	
EX18	5-Stage Esophageal Dilation Balloon 17-18-19-20-21 mm, 8 cm	Not Offered	
EPB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	Not Offered	
EPB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	Not Offered	
EPB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	Not Offered	
EPB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	Not Offered	
EPB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	Not Offered	
EB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	Not Offered	
EPCB6	3-Stage Wire Guided Dilation Balloon 6-7-8 mm, 5 cm	Not Offered	
EPCB8	3-Stage Wire Guided Dilation Balloon 8-9-10 mm, 5 cm	Not Offered	
EPCB10	3-Stage Wire Guided Dilation Balloon 10-11-12 mm, 5 cm	Not Offered	
EPCB12	3-Stage Wire Guided Dilation Balloon 12-13.5-15 mm, 5 cm	Not Offered	
EPCB15	3-Stage Wire Guided Dilation Balloon 15-16.5-18 mm, 5 cm	Not Offered	
ECB18	3-Stage Wire Guided Dilation Balloon 18-19-20 mm, 5 cm	Not Offered	

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