

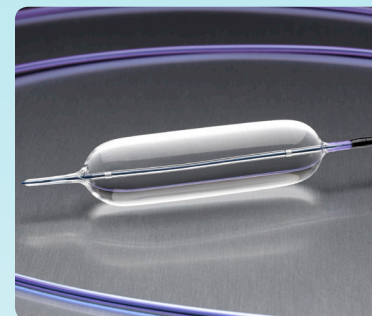
MaxForce TTS™ Esophageal High Performance Balloon Dilatation Catheter



CRE™ Fixed and Wireguided Balloon Dilatation Catheters



CRE PRO Wireguided Balloon Dilatation Catheter



FEATURES

- One size balloon

- Pebax material for 3 distinct dilation diameters with little-to-no balloon waisting
- Profile designed for improved scope compatibility
- Rounded shoulders to facilitate visualization of stricture

- Identical to the CRE Wireguided Balloon Dilatation Catheter, **PLUS platinum iridium RO markers** for fluoroscopic visualization and to facilitate proper positioning within a stricture

APPLICATIONS

- Esophageal dilation

- Fixed wire balloon dilation catheters for esophageal dilation
- Wireguided balloon dilatation catheters for esophageal, pyloric and colonic dilation

- Esophageal, pyloric, colonic and **biliary** dilation
- First balloon dilation catheter **indicated for use in the DASE** (dilation assisted stone extraction) procedure for removal of difficult biliary stones

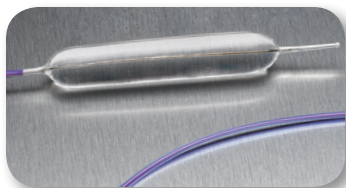
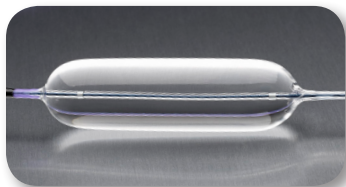
ECONOMIC BENEFITS

- Low cost option

- One balloon provides dilatation at 3 distinct sizes, which may reduce the need for additional balloons per procedure
- Available in a wide variety of sizes

- DASE may be an alternative to other complex stone management procedures (laser or electrohydraulic lithotripsy) and may help prevent the need for repeat ERCP
- Decreased inventory requirements; one balloon with many “anatomical” indications

Dilation Product Ordering Information



CRE™ PRO SINGLE-USE WIREGUIDED ESOPHAGEAL/PYLORIC/BILIARY BALLOON DILATION CATHETERS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|--------------|---------------|------------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00558600 | 6-7-8 | 18-21-24 | 5.5 | 3-6-10 | 2.8 / 3.2* | 7.5 | 180 |
| M00558610 | 8-9-10 | 24-27-30 | 5.5 | 3-5-9 | 2.8 / 3.2* | 7.5 | 180 |
| M00558620 | 10-11-12 | 30-33-36 | 5.5 | 3-5-8 | 2.8 / 3.2* | 7.5 | 180 |
| M00558630 | 12-13.5-15 | 36-40.5-45 | 5.5 | 3-4-5-8 | 2.8 / 3.2* | 7.5 | 180 |
| M00558640 | 15-16.5-18 | 45-49.5-54 | 5.5 | 3-4-5-7 | 2.8 / 3.2* | 7.5 | 180 |
| M00558650** | 18-19-20 | 54-57-60 | 5.5 | 3-4-5-6 | 2.8 / 3.2* | 7.5 | 180 |

CRE PRO SINGLE-USE WIREGUIDED ESOPHAGEAL/PYLORIC/COLONIC/BILIARY BALLOON DILATION CATHETERS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|--------------|---------------|------------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00558660 | 6-7-8 | 18-21-24 | 5.5 | 3-6-10 | 2.8 / 3.2* | 7.5 | 240 |
| M00558670 | 8-9-10 | 24-27-30 | 5.5 | 3-5-9 | 2.8 / 3.2* | 7.5 | 240 |
| M00558680 | 10-11-12 | 30-33-36 | 5.5 | 3-5-8 | 2.8 / 3.2* | 7.5 | 240 |
| M00558690 | 12-13.5-15 | 36-40.5-45 | 5.5 | 3-4-5-8 | 2.8 / 3.2* | 7.5 | 240 |
| M00558700 | 15-16.5-18 | 45-49.5-54 | 5.5 | 3-4-5-7 | 2.8 / 3.2* | 7.5 | 240 |
| M00558710*** | 18-19-20 | 54-57-60 | 5.5 | 3-4-5-6 | 2.8 / 3.2* | 7.5 | 240 |

CRE SINGLE-USE WIREGUIDED ESOPHAGEAL / PYLORIC BALLOON DILATORS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|---------------|---------------|------------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00558390 | 6-7-8 | 18-21-24 | 5.5 | 3-6-10 | 2.8 | 7.5 | 180 |
| M00558400 | 8-9-10 | 24-27-30 | 5.5 | 3-5-9 | 2.8 | 7.5 | 180 |
| M00558410 | 10-11-12 | 10-11-12 | 5.5 | 3-5-8 | 2.8 | 7.5 | 180 |
| M00558420 | 12-13.5-15 | 12-13.5-15 | 5.5 | 3-4-5-8 | 2.8 | 7.5 | 180 |
| M00558430 | 15-16.5-18 | 15-16.5-18 | 5.5 | 3-4-5-7 | 2.8 | 7.5 | 180 |
| M00558440**** | 18-19-20 | 18-19-20 | 5.5 | 3-4-5-6 | 2.8 | 7.5 | 180 |

CRE SINGLE-USE WIREGUIDED ESOPHAGEAL/PYLORIC/COLONIC BALLOON DILATORS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|----------------|---------------|------------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00558450 | 6-7-8 | 18-21-24 | 5.5 | 3-6-10 | 2.8 | 7.5 | 240 |
| M00558460 | 8-9-10 | 24-27-30 | 5.5 | 3-5-9 | 2.8 | 7.5 | 240 |
| M00558470 | 10-11-12 | 30-33-36 | 5.5 | 3-5-8 | 2.8 | 7.5 | 240 |
| M00558480 | 12-13.5-15 | 36-40.5-45 | 5.5 | 3-4-5-8 | 2.8 | 7.5 | 240 |
| M00558490 | 15-16.5-18 | 45-49.5-54 | 5.5 | 3-4-5-7 | 2.8 | 7.5 | 240 |
| M00558500***** | 18-19-20 | 54-57-60 | 5.5 | 3-4-5-6 | 2.8 | 7.5 | 240 |

CRE SINGLE-USE FIXED WIRE BALLOON DILATORS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|--------------|---------------|------------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00558330 | 6-7-8 | 18-21-24 | 8 | 3-6-10 | 2.8 | 6 | 180 |
| M00558340 | 8-9-10 | 24-27-30 | 8 | 3-5-9 | 2.8 | 6 | 180 |
| M00558350 | 10-11-12 | 30-33-36 | 8 | 3-5-8 | 2.8 | 6 | 180 |
| M00558360 | 12-13.5-15 | 36-40.5-45 | 8 | 3-4-5-8 | 2.8 | 6 | 180 |
| M00558370 | 15-16.5-18 | 45-49.5-54 | 8 | 3-4-5-7 | 2.8 | 6 | 180 |
| M00558380 | 18-19-20 | 54-57-60 | 8 | 3-4-5-6 | 2.8 | 6 | 180 |
| M00558361 | 12-13.5-15 | 36-40.5-45 | 8 | 3-4-5-8 | 2.8 | 6 | 180 |
| M00558371 | 15-16.5-18 | 45-49.5-54 | 8 | 3-4-5-7 | 2.8 | 6 | 180 |
| M00558381 | 18-19-20 | 54-57-60 | 8 | 3-4-5-6 | 2.8 | 6 | 180 |

Recommended Inflation Device: Alliance™ II Integrated Inflation System Handle Order #5062, Sterile Syringe Order #5060.

Guidewire included and preloaded in balloon catheter.

* Duodenoscope Channel Size

** Esophageal and Biliary application only

*** Esophageal, Colonic and Biliary application only

**** Esophageal application only

***** Esophageal and Colonic application only

MAXFORCE™ AND RIGIFLEX™ BALLOON DILATORS ALSO AVAILABLE

MAXFORCE TTS SINGLE-USE ESOPHAGEAL BALLOON DILATORS

| Order Number | Inflated O.D. | | Balloon Length (cm) | Inflation Pressured (ATM) | Minimum Working Channel (mm) | Catheter Size (Fr) | Working Length (cm) |
|--------------|---------------|------|---------------------|---------------------------|------------------------------|--------------------|---------------------|
| | (mm) | (Fr) | | | | | |
| M00589060 | 6 | 18 | 6 | 10 | 2.8 | 6 | 180 |
| M00589080 | 8 | 24 | 6 | 10 | 2.8 | 6 | 180 |
| M00589100 | 10 | 30 | 6 | 7 | 2.8 | 6 | 180 |
| M00589120 | 12 | 36 | 6 | 7 | 2.8 | 6 | 180 |
| M00589140 | 14 | 42 | 6 | 7 | 2.8 | 6 | 180 |
| M00589150 | 15 | 45 | 6 | 5 | 2.8 | 6 | 180 |
| M00589160 | 16 | 48 | 6 | 5 | 2.8 | 6 | 180 |
| M00589180 | 18 | 54 | 6 | 5 | 2.8 | 6 | 180 |

Recommended Inflation Device: Alliance™ II Integrated Inflation System Handle Order #5062, Sterile Syringe Order #5060.

RIGIFLEX II SINGLE-USE ACHALASIA BALLOON DILATORS†

| Order Number | Inflated O.D. | | Balloon Length (cm) | Catheter Size (Fr) | Working Length (cm) | Recommended Guidewire‡ |
|--------------|---------------|------|---------------------|--------------------|---------------------|------------------------|
| | (mm) | (Fr) | | | | |
| M00554500 | 30 | 90 | 10 | 14 | 90 | .038" |
| M00554510 | 35 | 105 | 10 | 14 | 90 | .038" |
| M00554520 | 40 | 120 | 10 | 14 | 90 | .038" |

† Product shipped sterile.

‡ Guidewire included with RigiFlex II Balloon Dilator Catheter.

Recommended use with Achalasia Pneumatic Hand Pump and Monitor Order #5320

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Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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