

# TECHNICAL SPECIFICATIONS

Kyphoplasty Balloon Catheter System

## BALLOON SPECIFICATION

| Description      | Initial Length (mm) | Rated Pressure (PSI) | Max. Inflation Volume (cc) | Max. Diameter (mm) | Max. Length (mm) |
|------------------|---------------------|----------------------|----------------------------|--------------------|------------------|
| Spino Balloon 15 | 15                  | 300                  | 4                          | 17                 | 22               |

## RADIFLATOR SPECIFICATION

| Description | Max. Allowable Pressure (PSI) | Max. Syringe Capacity (cc) | Pressure Holding Time (sec) |
|-------------|-------------------------------|----------------------------|-----------------------------|
| Radiflator  | 400                           | 30                         | 30                          |

## BONJECTOR SPECIFICATION

| Description   | Total Length (mm) | Gauge |
|---------------|-------------------|-------|
| Bonjector 11G | 176               | 11G   |
| Bonjector 13G | 176               | 13G   |

## POP COMPONENT SPECIFICATION

| Component                 | Total Length (mm) | Diameter (mm) |
|---------------------------|-------------------|---------------|
| Obturator                 | 180               | 3.5           |
| Cannula                   | 155               | 4.2           |
| Bone Drill                | 235               | 3.5           |
| Cement Injection Device A | 215               | 3.4           |
| Cement Injection Device B | 255               | 2.7           |
| Guide Wire                | 257               | 1.5           |

## POP KIT COMPOSITION

| Component                 | POP-A | POP-B |
|---------------------------|-------|-------|
| Obturator                 | 1     | 1     |
| Cannula                   | 2     | 1     |
| Bone Drill                | 1     | 1     |
| Cement Injection Device A | 6     | 3     |
| Cement Injection Device B | 6     | 3     |
| Guide Wire                | 2     | 1     |

# Kyphoplasty Balloon Catheter System

# Spino Balloon 15



## INDICATIONS

- Vertebral compression fractures due to osteoporosis
- Osteolytic fractures
- Metastatic bone fractures

## SURGI BIO

ISO 13485-certified QMS  
KGMP-certified manufacturing facility  
Single-use, EO-sterilized devices

*Detailed documentation available upon request*

## SPINO BALLOON 15



- Initial balloon length: 15 mm
- Maximum inflation volume: 4 cc
- Rated pressure: 300 PSI
- Maximum diameter / length: 17 / 22 mm

## RADIFLATOR - BALLOON INFLATION DEVICE



- Maximum allowable pressure: 400 PSI
- Pressure holding time: 30 seconds
- Maximum syringe capacity: 30 cc
- 3-way connector and pressure release button

SINGLE USE

EO STERILIZED

ISO 13485:2016

KGMP

## POP-A / POP-B ACCESS SYSTEM

POP-A supports the two-balloon set. POP-B supports the one-balloon set.

### 1. Obturator / Cannula



### 2. Bone Drill



### 3. Cement Injection Device



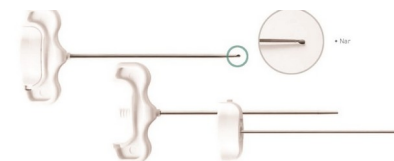
### 4. Guide wire



Cement Injection Devices A and B are supplied as separate components.

See page 1 for detailed POP-A / POP-B component quantities.

## BONJECTOR - BONE MARROW NEEDLE



- Available in 11G and 13G
- Total length: 176 mm
- Single-use, EO sterilized

Bone cement is available separately and is not included in the standard set.