

Dénomination commerciale :

Pistolet pour microbiopsie MaxCore®


Indications :

Micro-biopsie des tissus mous (ex : sein, prostate, poumon, foie, rein...) pour diagnostic différentiel

Particularités d'utilisation :

- Armement du pistolet à une main
- Choix de déclenchement du tir par un bouton situé à l'arrière de la poignée ou un bouton latéral
- Taille codée par couleur

| Référence | Taille (G) / Code couleur | Longueur (cm) | Compatible avec aiguille Truguide* | Référence TruGuide™ correspondante |
|-----------|---------------------------|---------------|------------------------------------|------------------------------------|
| MC1410 | 14 / vert | 10 | 7.8 cm | C1410A |
| MC1416 | 14 / vert | 16 | 13.8 cm | C1416A |
| MC1610 | 16 / violet | 10 | 7.8 cm | C1610A |
| MC1616 | 16 / violet | 16 | 13.8 cm | C1616A |
| MC1810 | 18 / rose | 10 | 7.8 cm | C1810A |
| MC1816 | 18 / rose | 16 | 13.8 cm | C1816A |
| MC2010 | 20 / jaune | 10 | 7.8 cm | C2010A |
| MC2016 | 20 / jaune | 16 | 13.8 cm | C2016A |
| MC2020 | 20 / jaune | 20 | 17.8 cm | C2020A |

Principaux éléments constitutifs et nature des matériaux :

| Éléments | Matériaux |
|------------------------------|--|
| Pistolet + aiguille monobloc | |
| Poignée | - Coque : Polyester |
| | - Glissière d'armement : Polycarbonate |
| | - Boutons de déclenchement : Acétal |
| Aiguille | Acier inoxydable |

Origine animale : Non
 Latex : Non
 Phtalates : Non

Marquage CE :

Organisme notifié : BSI (0086)
 Numéro de certificat : 01467
 Classe du produit : CE Classe IIa
 Date : 17/10/2008 - Validité : 04/12/2011

Fabricant : Bard Peripheral Vascular, Inc
 Lieu : Tempe (USA)
 Référentiel : ISO 13485 : 2003
 Organisme notifié : BSI (0086)
 Numéro de certificat : FM92806
 Date : 05/01/2005 - Validité : 09/11/2013

Code GMDN : 36190
 Code LPPR : N/A
 TVA : 19,6%

Stérilisation / Péréemption :

Usage unique : Oui
 Stérile : Oui
 Mode de stérilisation : Oxyde d'éthylène
 Lieu de stérilisation : USA
 Péréemption : 3 ANS

Conditionnement :

Unité d'emploi (par sachet stérile) : 1
 Unité protégée (d'emploi par boîte) : 5
 Unité de vente : 5
 Nature emballage : PVC / TYVEK

Informations complémentaires :

Longueur entre l'extrémité distale de l'encoche et la pointe de l'aiguille :

pour une aiguille de : 14 G => 5,8 mm

16 G => 5,0 mm

18 G => 5,0 mm

20 G => 3,8 mm

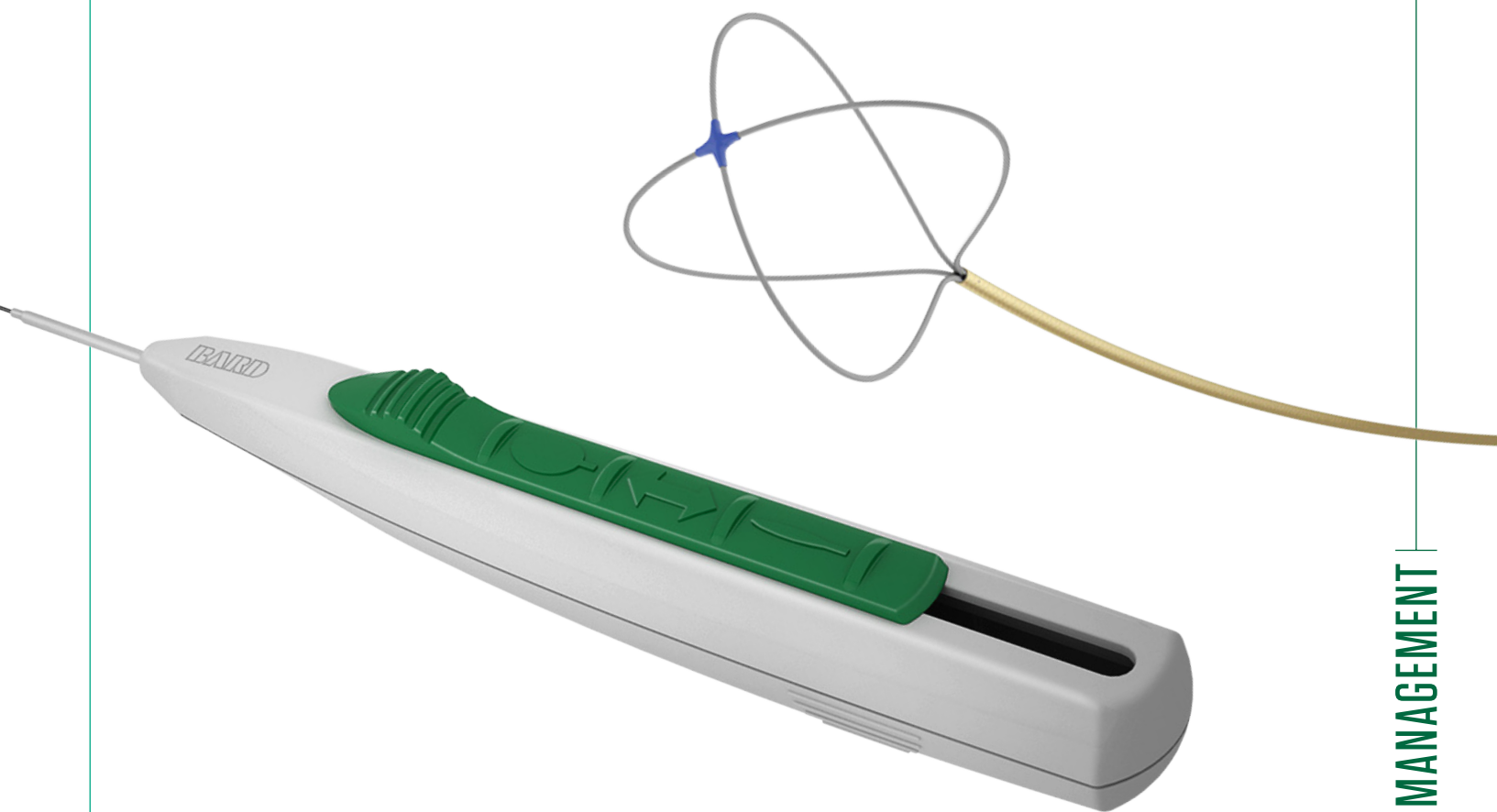
STONE BASKETS

Featuring
VisiBlue™
Technology

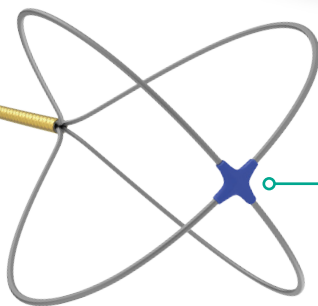
SKYLITE™

1.9 FR. TIPLESS NITINOL STONE BASKET

Engineered for enhanced
endoscopic visibility.



STONE MANAGEMENT



VisiBlue™ Technology

The BARD® SKYLITE™ Tipless Nitinol Stone Basket is engineered to enhance visibility under endoscopic light.

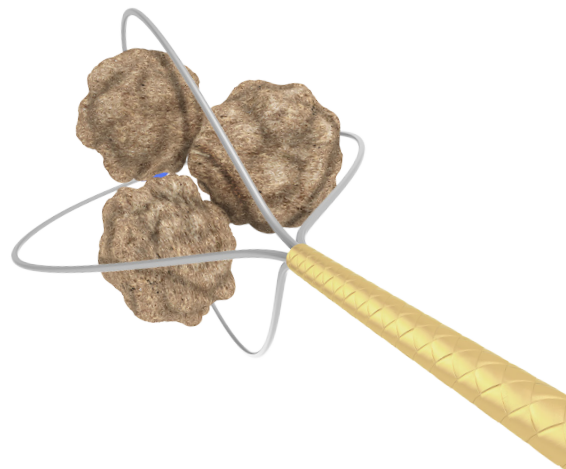
SKYLITE™

1.9 FR. TIPLESS NITINOL STONE BASKET

The BARD® SKYLITE™ Tipless Nitinol Stone Basket features a “no tip” basket designed to help with atraumatic retrieval of stones in the ureter and calyces.

Flexibility. Durability.

- Designed for reliable and durable performance in a fully deflected flexible ureteroscope.
- The spring loaded sheath is designed to protect the basket from damage or distortion during stone retrieval.
- Constructed of Nitinol, the SKYLITE™ Basket offers a kink-resistant design, to help with stone extraction.
- Allows for full 270° deflection of a flexible ureteroscope.



Ordering Information

| Order No. | Sheath | Working Length (cm) | Basket Diameter (mm) |
|-----------|--------|---------------------|----------------------|
| 041900 | 1.9 | 120 | 12 |

Please consult package insert for more detailed safety information and instructions for use.

DESCRIPTION: The BARD® SKYLITE™ Tipless Nitinol Stone Basket consists of a handle to open, close and rotate the basket, a flexible polyimide shaft and a 4-wire nitinol stone basket. The package includes one (1) basket and one (1) introducer. **INDICATIONS FOR USE:** This device is intended for use in endoscopic removal of ureteral and renal stones. **CONTRAINDICATIONS:** None known **Warnings:** • Some objects may be too large to be removed endoscopically using a retrieval device. The use of fluoroscopy and/or x-ray to determine the size of the object is recommended. Do not use the BARD® SKYLITE™ Tipless Nitinol Stone Basket if the object is too large to be removed endoscopically, as it may • result in patient injury and pain. • This is a single use device. Do not resterilize any portion of this device. Reuse and/or repackaging may • create a risk of patient or user infection, compromise the structural integrity and/or essential material and • design characteristics of the device, which may lead to device failure, and/or may lead to injury, illness or • death of a patient. Do not attempt to repair, reassemble, or alter the device in any way. • After use, this product will be a potential biohazard. Handle and dispose of in accordance with accepted medical practices and with applicable laws and regulations. Follow your institutional guidelines. **CAUTION:** Objects that are too large to be removed through the scope channel will require the scope and basket to be removed simultaneously from the urinary tract. If resistance is encountered during advancement or withdrawal of the device, stop and determine the source of resistance, as continued resistance may damage the device and could result in patient injury. Take action to alleviate the resistance. **PRECAUTIONS:** Before using, inspect for any breach of packaging to ensure sterility of product. Do not use if breach in sterile barrier is obvious or suspected. Do not allow the device to come in contact with any electrified instruments or laser. Kinks in the sheath will hinder the mechanical operation of the basket, may affect insertion or withdrawal of the basket and has the potential to damage the endoscope's instrument channel. Do not allow the device to be directly fired upon by any lithotripsy devices. To do so may result in damage to the device and could result in patient injury. Potential complications that may result from the use of a basket in an endoscopic urological procedure include, but are not limited to: • Perforation • Evulsion • Edema • Entrapment • Laceration • Basket Inversion • Hemorrhage • Inability to disengage from irretrievable object

For ordering information contact:

| | |
|-----------------------|---|
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