

Bard® SkyLite™

Tipless Nitinol Stone Basket

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BAIRD



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CE
2797

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Bard® SkyLite™ Tipless Nitinol Stone Basket

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,

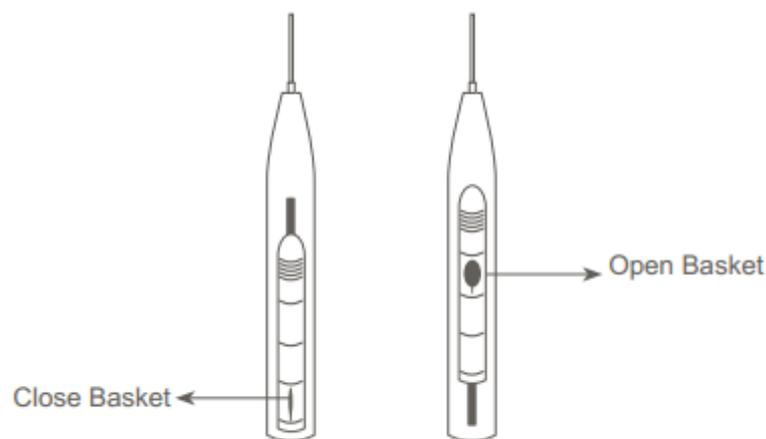
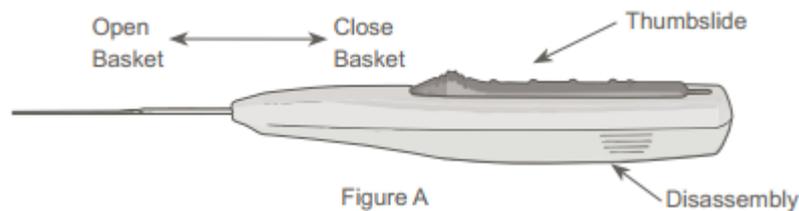
but are not limited to:

- Perforation
- Evulsion
- Edema
- Entrapment
- Laceration
- Basket Inversion
- Hemorrhage
- Inability to disengage from irretrievable object

Directions for Use:

Only physicians trained in stone manipulation should perform this procedure. A variety of techniques may

be employed; however the physician should use the technique most appropriate for the individual patient's situation.



Insertion

1. Inspect the device prior to use and during the procedure for integrity and function.
2. Make sure the basket is closed by retracting (pulling back) the basket tip into the sheath with the thumb slide as shown in Figure B.
3. With the basket closed, and using the optional introducer provided, carefully advance the distal portion of the closed device through the endoscope until it emerges out of the end of the endoscope.

Capture and Removal

1. Under direct vision or fluoroscopic guidance, slowly advance the basket tip past the object.
2. Open the basket by pushing the thumb slide forward. (Refer to Figure B).
3. Pull the basket backward toward the object while slowly rotating the basket as necessary.
4. Once the object has been captured, partially close the basket to secure the object for removal by carefully pulling the thumb slide back. (Refer to Figure B).
5. Slowly remove the basket and stone from the urinary tract.
6. If the object is too large, you may need to simultaneously withdraw the basket and the ureteroscope from the urinary system.

Directions for Disassembly

If handle disassembly is desired or required:

1. Squeeze bottom handle half at indicated points and pull down to remove handle bottom.
2. Loosen thumbscrew until basket drive wire moves freely.
3. Slide sheath and handle assembly over and away from drive wire.

LOT

Lot number
 Numéro de lot
 Los-Nummer
 Numero di lotto
 Número de lote
 Lotnummer
 Número do lote
 Αριθμός παρτίδας
 Lotnummer
 Lot-nummer
 Eränumero
 Lotnummer
 Numer serii
 Tételszám
 Číslo šarže
 Partii numarası
 Номер серии
 批次編號
 로트 번호



Use by
 Printed on
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 Printed by
 REF

Verwendbar bis
 Usare entro
 Usar antes de
 Te gebruiken vóór
 Prazo de validade
 Ημερομηνία λήξης
 Anvendes før
 Utgångsdag
 Käytettävä ennen
 Brukes innen
 Termin ważności
 Felhasználható
 Datum použitelnosti
 Son kullanim tarihi
 Исползовать до
 使用期限
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 Gyártó
 Výrobce
 Üretici
 Производитель
 製造商
 제조사



Single Use
 Usage unique
 Nicht erneut sterilisieren
 Monouso
 Un solo uso
 Voor eenmalig gebruik
 Uso único
 Μίας χρήσης
 Till engangsbrug
 För engangsbruk
 Kertäkäyttöinen
 Till engangsbruk
 Do jednorazowego użytku
 Egyszer használatos
 K jednorázovému použití
 Tek Kullanımlıdır
 Для однократного применения
 單次使用
 일회용



Open Basket
 Ouverture du panier
 Körbchen öffnen
 Cestello aperto
 Abrir cesta
 Mandje open
 Abrir cesto
 Άνοιγμα καλαθιού
 Åbn stenfangner
 Öppna korg
 Avaa kori
 Åpne kurv
 Otwórz koszyk
 Kosár zárása
 Otevřít košíček
 Sepeti Aç
 Раскрыть корзину
 打開網籃
 바스켓 열기



Close Basket
 Fermeture du panier
 Körbchen schließen
 Cestello chiuso
 Cerrar cesta
 Mandje gesloten
 Fechar cesto
 Κλείσιμο καλαθιού
 Luk stenfangner
 Stäng korg
 Sulje kori
 Lukk kurv
 Zamknij koszyk
 Kosár zárása
 Zavřít košíček
 Sepeti Kapat
 Закрывать корзину
 閉合網籃
 바스켓 닫기

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