

Dormia® DualPerc

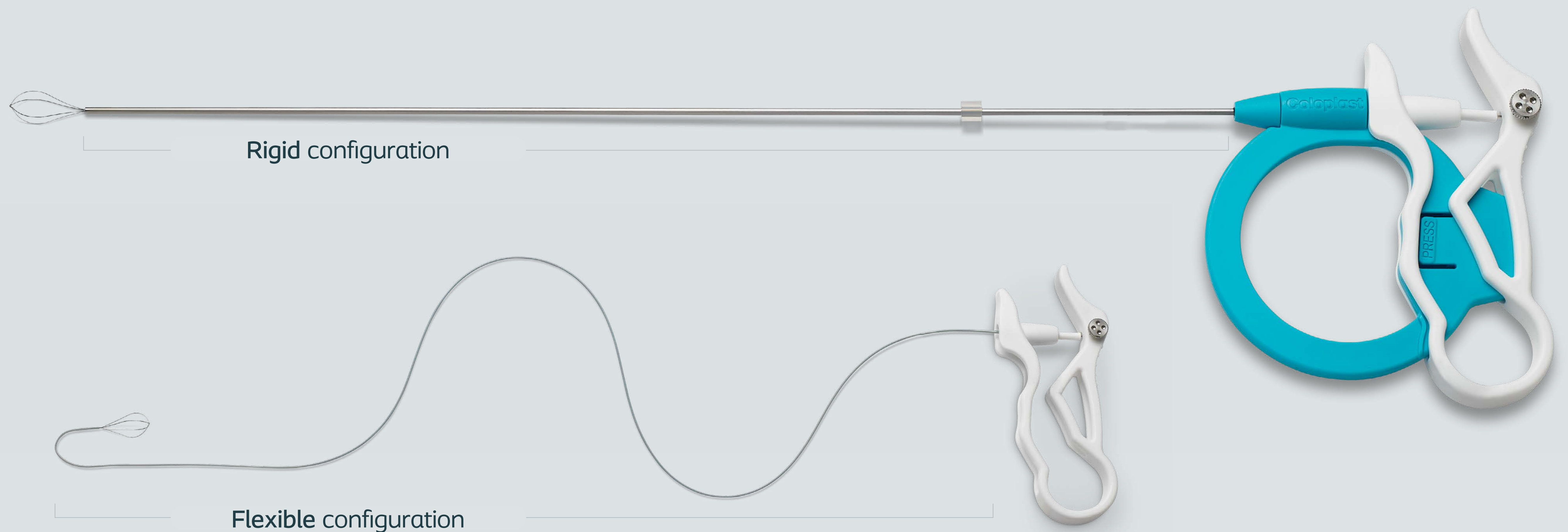
PCNL Basket

Two solutions.
One move.

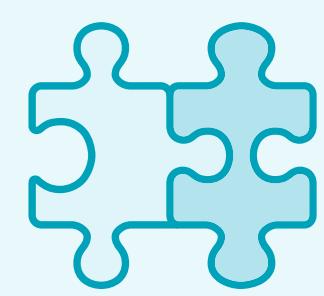


2-in-1 transformable device

Can be used as a *rigid* or a *flexible* stone extractor for PCNL

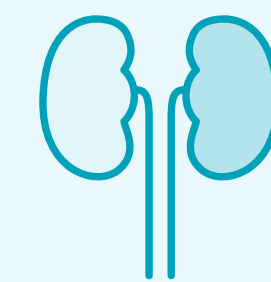


Main features



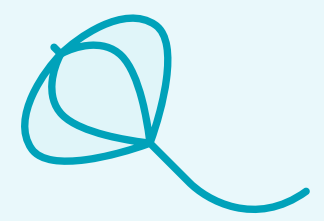
Unique concept

One device with two configurations for use with rigid and flexible nephroscope/cystoscope



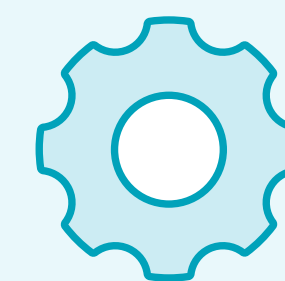
Enabling stone-free rates

Dual-purpose rigid and flexible design enables immediate removal of residual fragments



Enhanced procedural versatility

Smaller diameters than other PCNL extractors allow Dormia DualPerc to adapt to a wider range of PCNL procedures



Reduced waste and inventory optimization



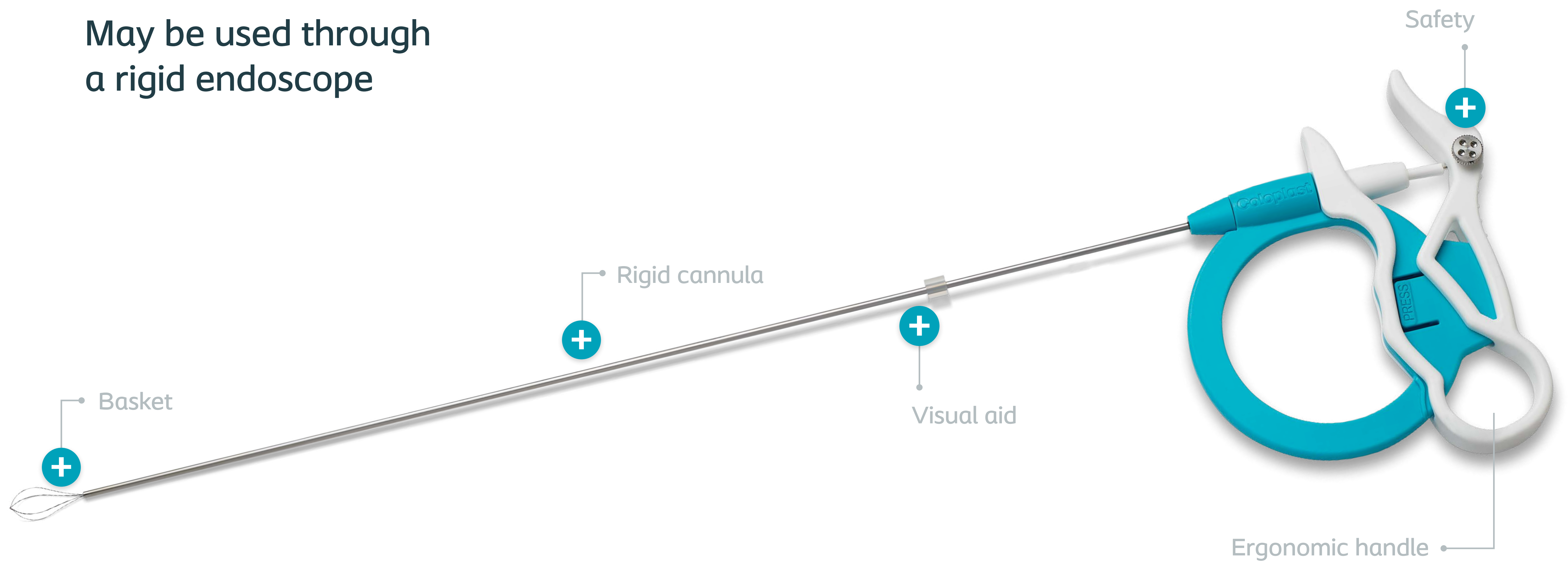
Design

2 sizes designed for both mini PCNL in 4.8Ch/Fr and standard PCNL in 7Ch/Fr



Rigid configuration

May be used through a rigid endoscope



Rigid configuration



Ergonomic handle

Optimum control of the basket positioning and responsive torque design

Ergonomic handling allowing different handling possibilities during manipulation for user comfort

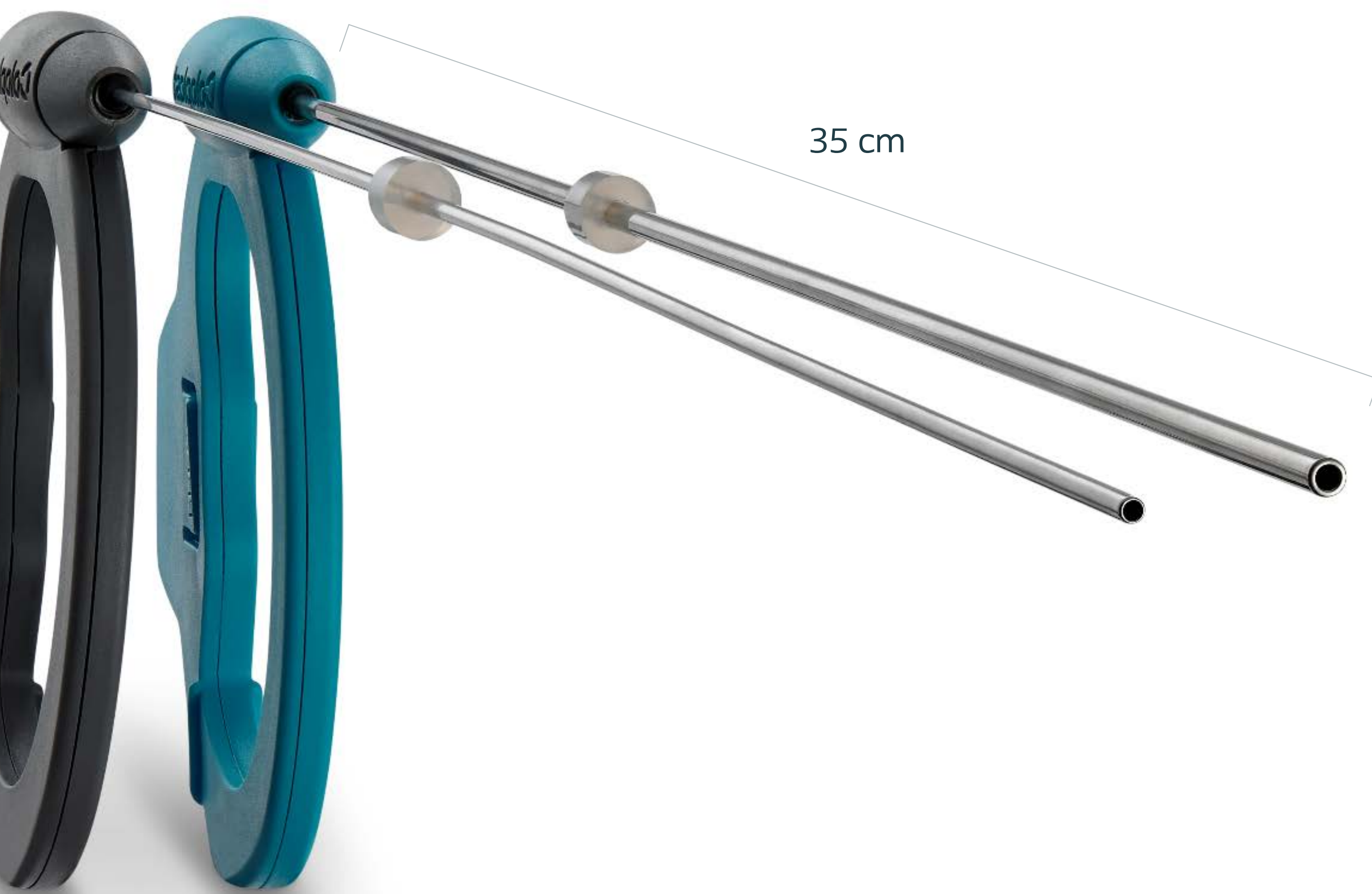


Color-coded handle to easily differentiate diameter size

Turquoise: 7Ch/Fr

Grey: 4.8Ch/Fr

Rigid configuration



Rigid cannula

7Ch/Fr compatible with **Standard PCNL**
4.8Ch/Fr compatible with **Mini PCNL**
(diameter and length)

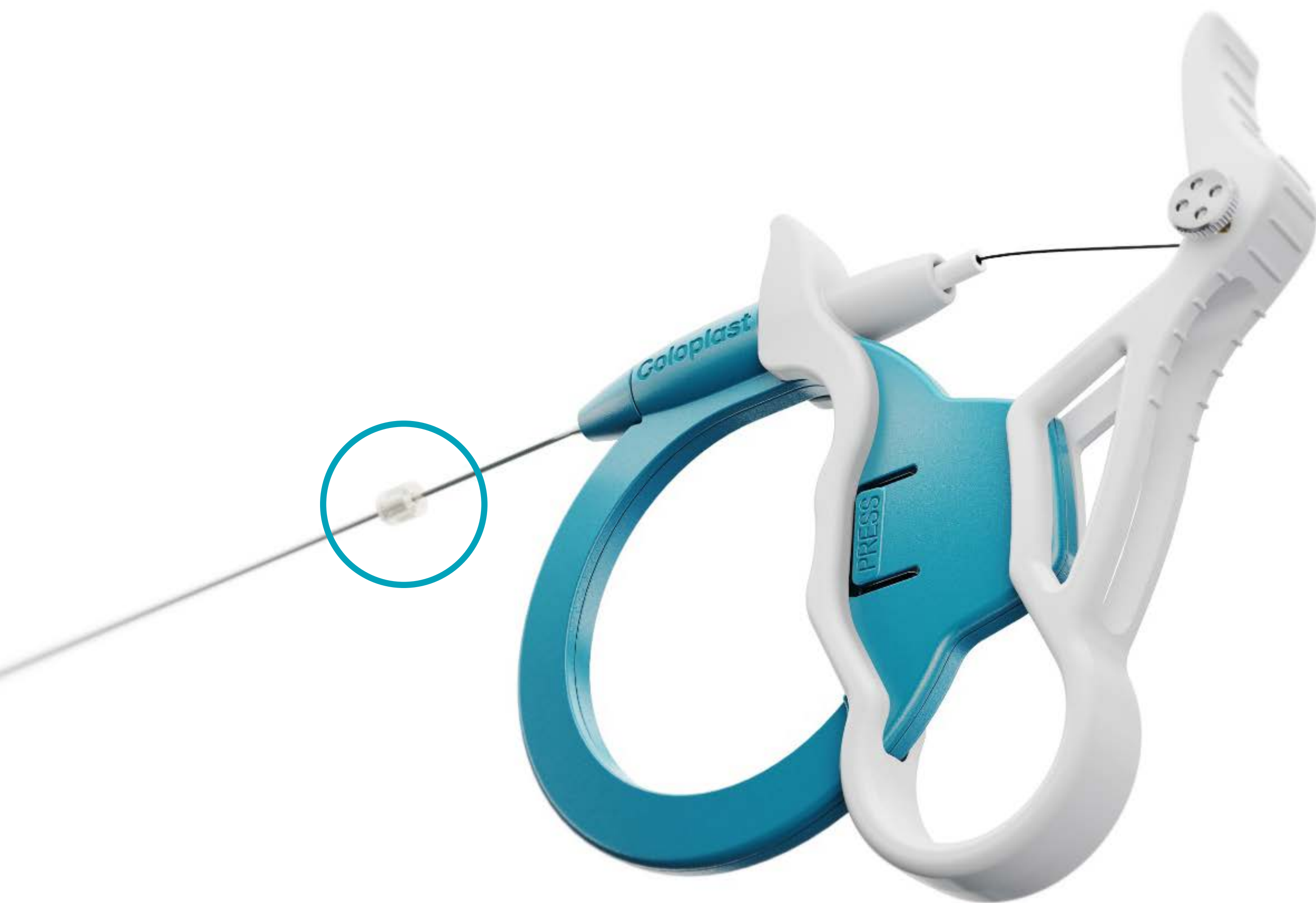
Adapted for the stone extraction in the calyces, renal pelvis and ureteropelvic junction

Stainless-steel cannula with rounded distal tip: for smoother contact with the tissue and instruments, designed to minimize trauma

Radiopaque tube: for accurate visualization under x-ray

Improved irrigation flow: compared to Cook Perc NCircle[®] in the same nephroscope working channel

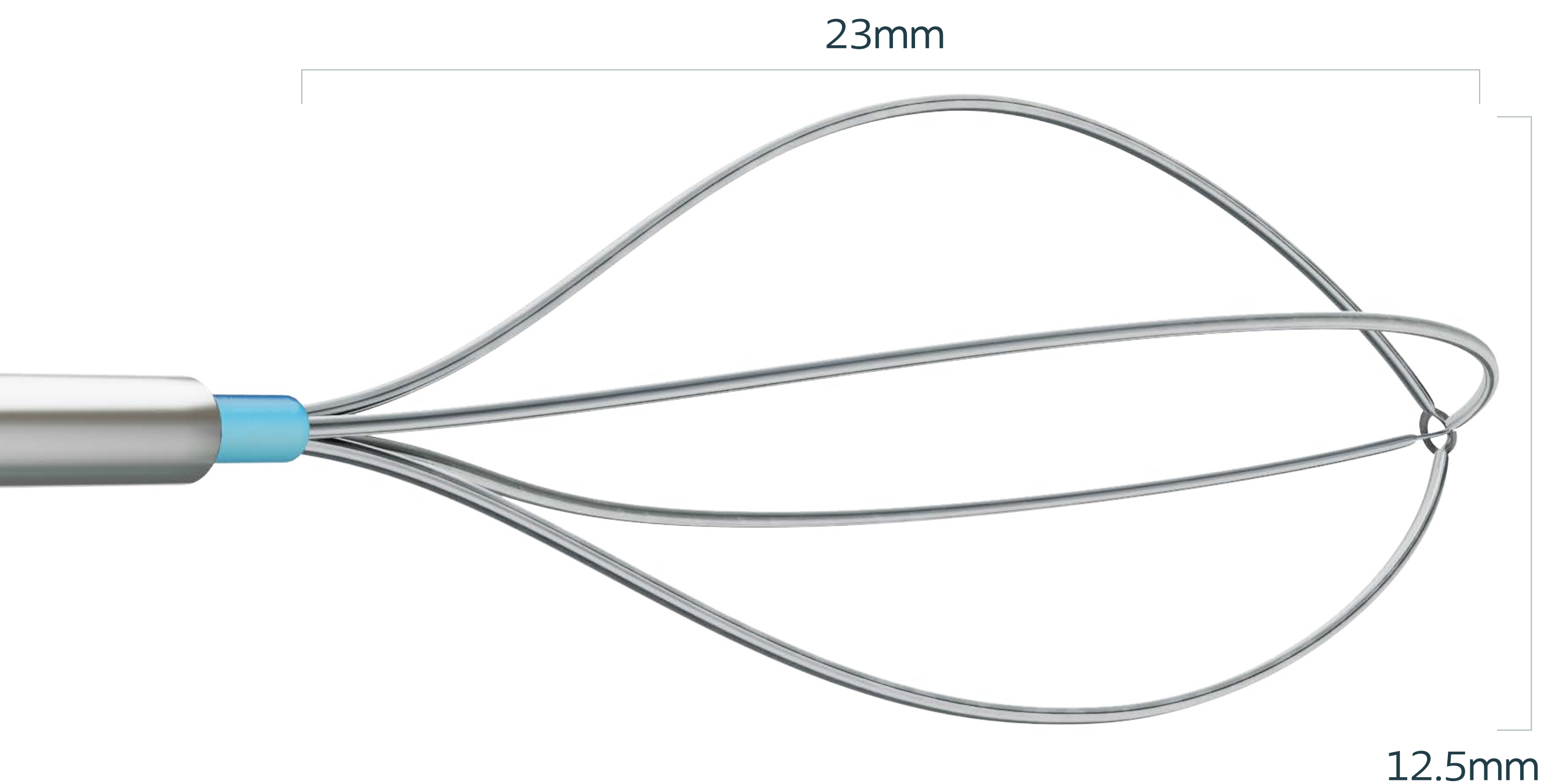
Rigid configuration



Visual aid

Movable silicone marker to indicate working position depth as defined by the operator and provide visual aid throughout the procedure

Rigid configuration



Basket

Nitinol basket: super elasticity and maximum shape memory

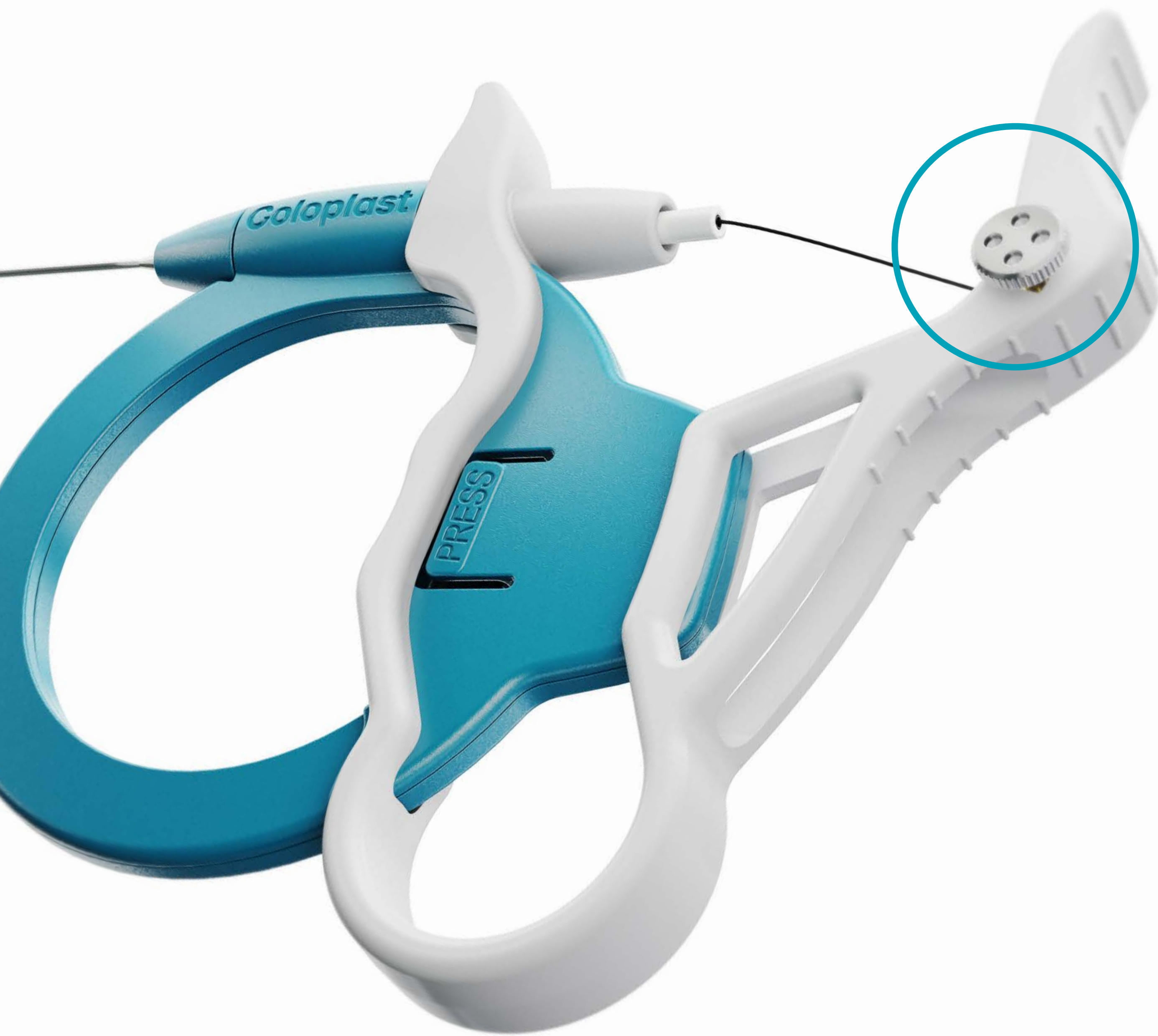
4 wires cage: for capture and retrieval of stones of different sizes and volumes

Tipless design: for direct contact against tissues with minimal trauma

Specific design:
for adapted opening
in small cavities



Rigid configuration



Safety

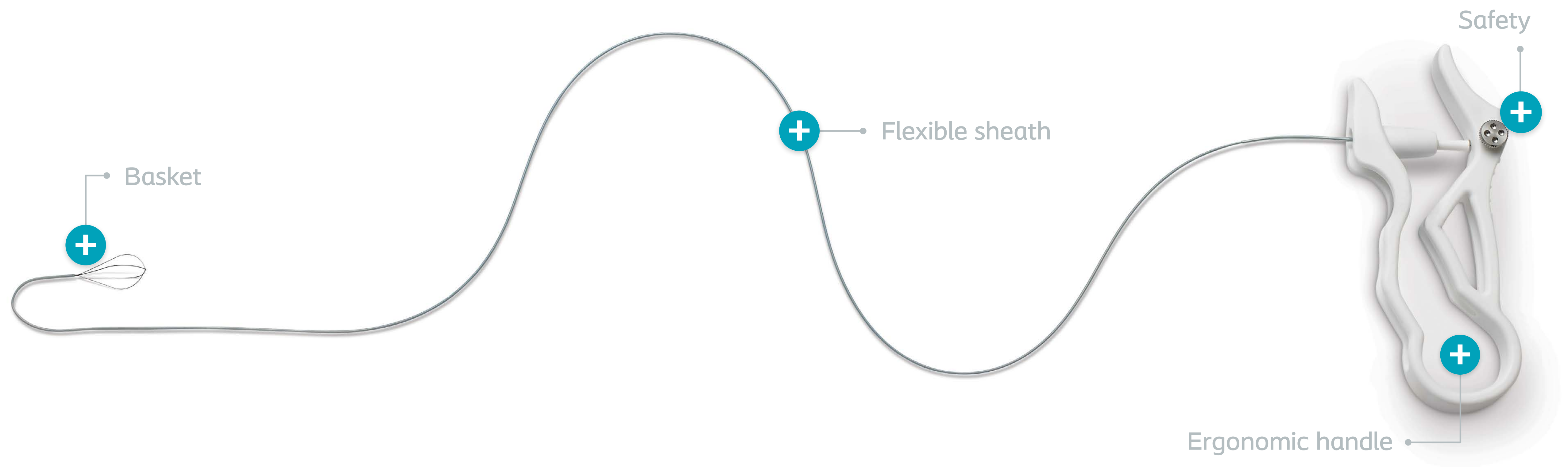
Emergency situation in case a stone cannot be released from the basket:

- Unscrew the screw and free the metallic part
- Remove the handle, the cannula and the sheath
- Mount and push laser fiber through endoscope working channel
- Fragment the trapped stone without damaging the basket
- Remove laser fiber
- Gently shake the basket forward and backward to spread the calculus debris
- Gently remove basket and endoscope

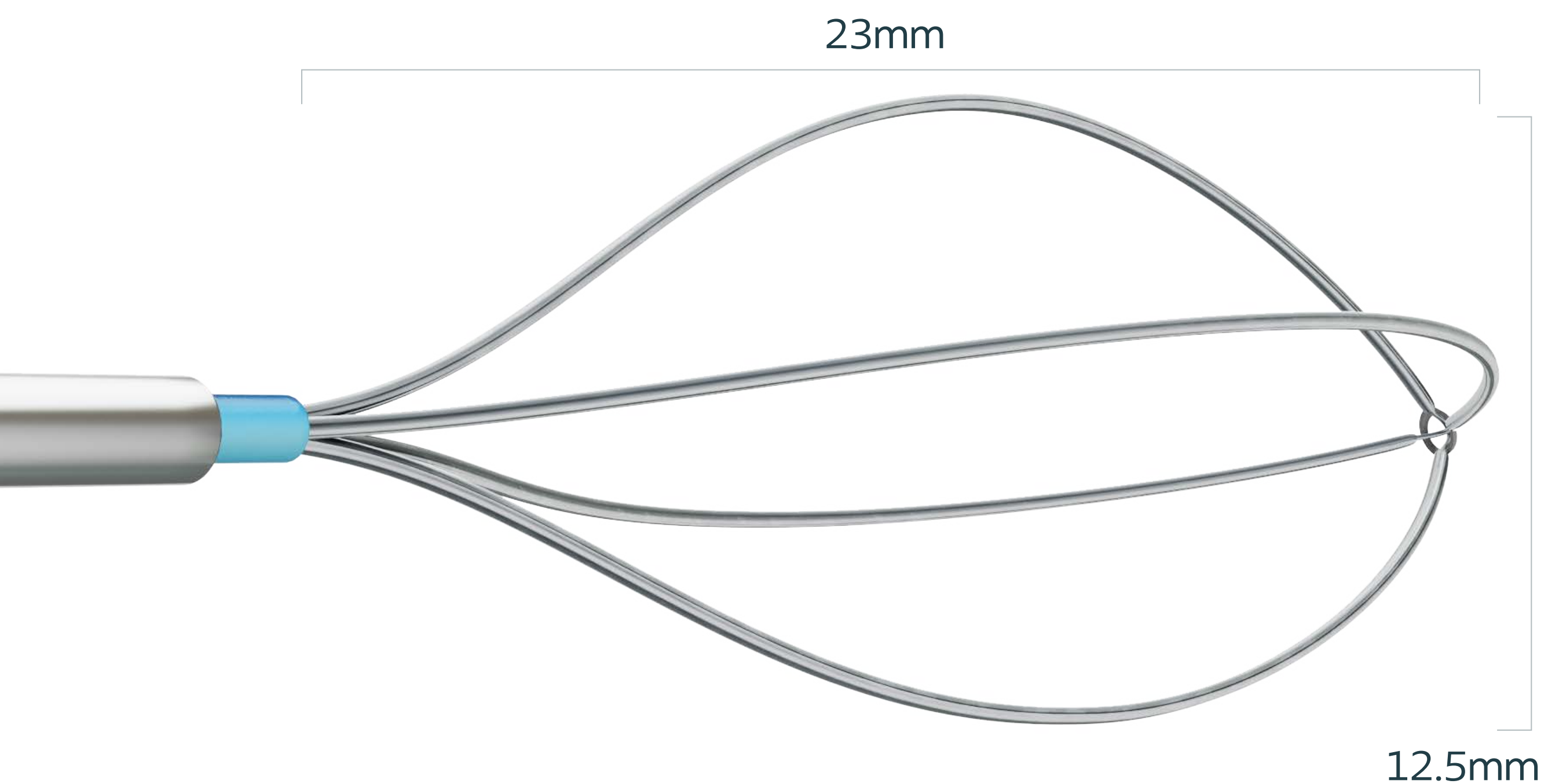
Warning: Once the device is dismantled, never refit the device for reuse. Use another device to complete the intervention

Flexible configuration

May be used through a flexible/
semi-rigid endoscope



Flexible configuration



Basket

Nitinol basket: super elasticity and maximum shape memory

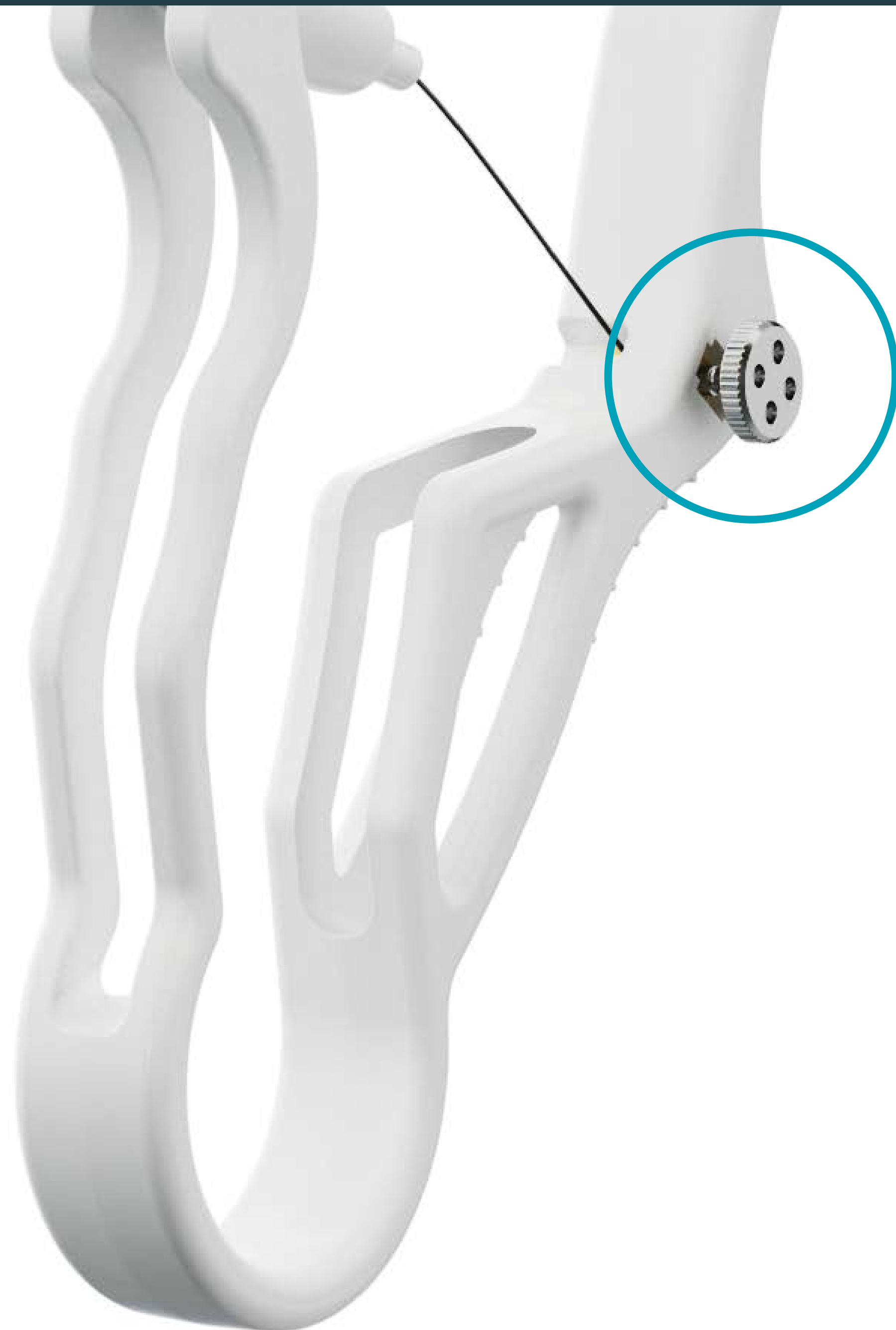
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Flexible configuration



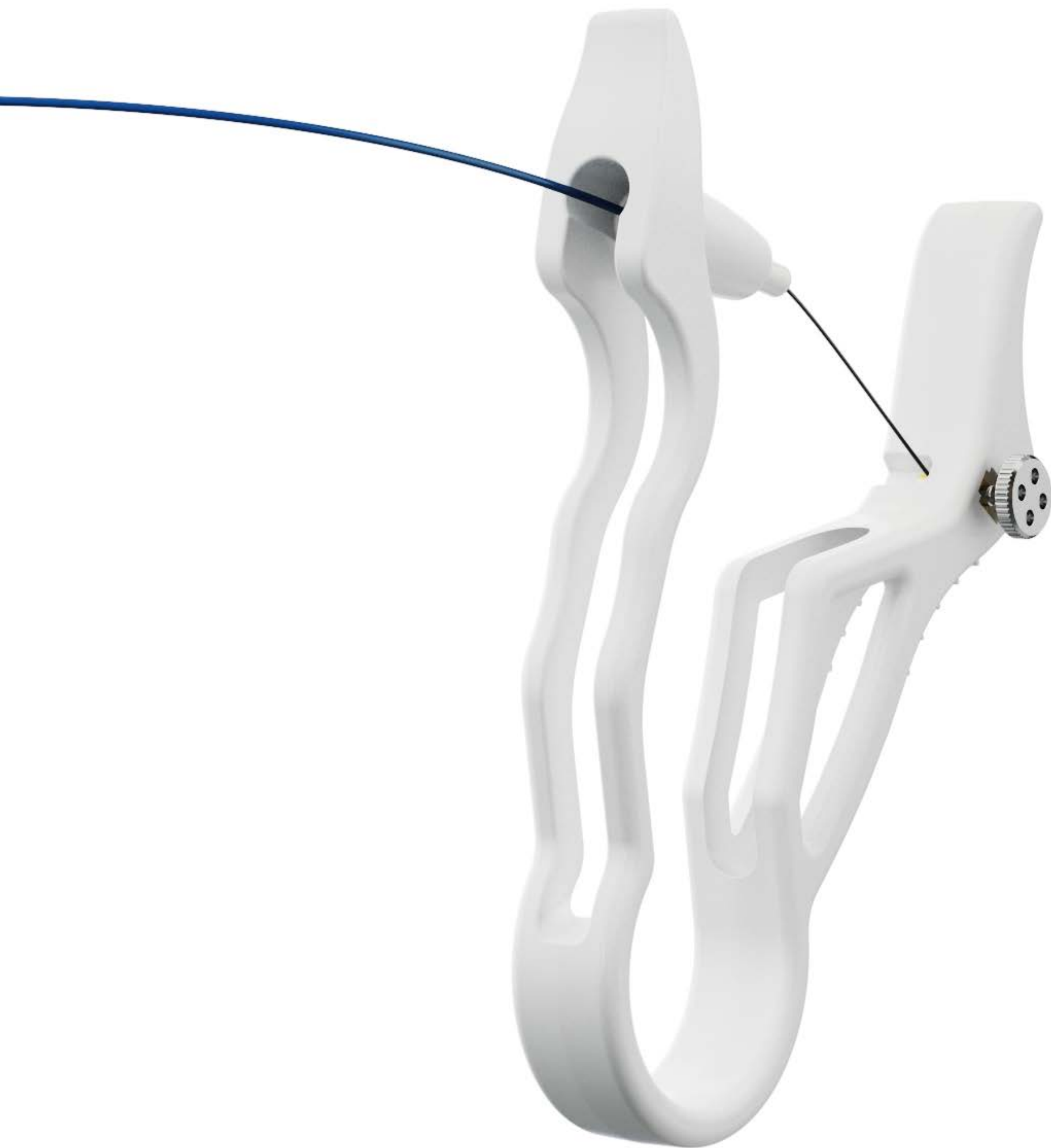
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Flexible configuration



Ergonomic handle

Optimum control of the basket positioning and responsive torque design

Made of PolyOxyMethylene (POM) material, fatigue resistant

Ergonomic handling, allowing different handling possibilities during manipulation

Solo operator use, product can be handled with one hand

Flexible configuration

Flexible sheath

3 Ch/Fr and 64cm long flexible sheath

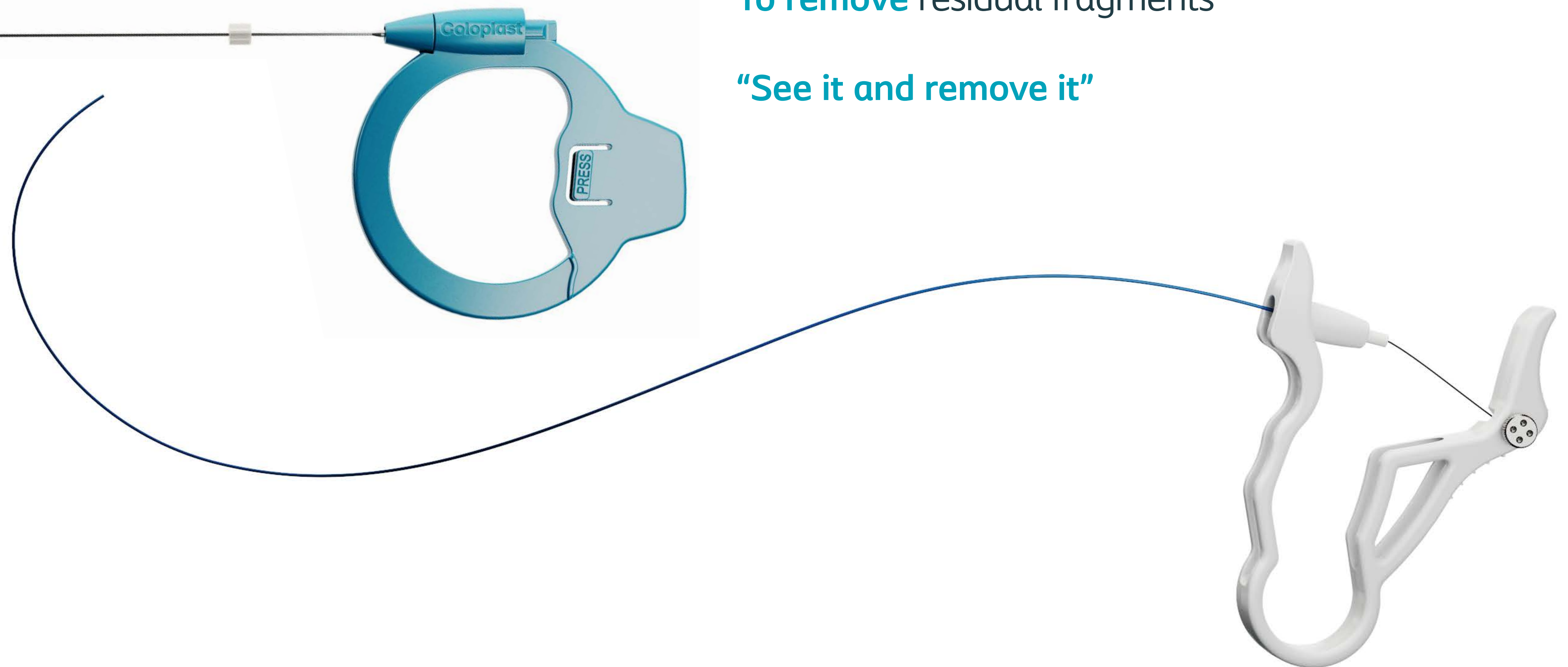
Working length designed for **optimal compatibility** with flexible cystoscope

Diameter of the sheath and mandrel permits **full deflection** of the flexible cystoscope during stone extraction



Reversibility

 Easily switch between configurations



Two-in-one device allows

Exploration of multiple renal cavities through only one percutaneous access

To remove residual fragments

“See it and remove it”

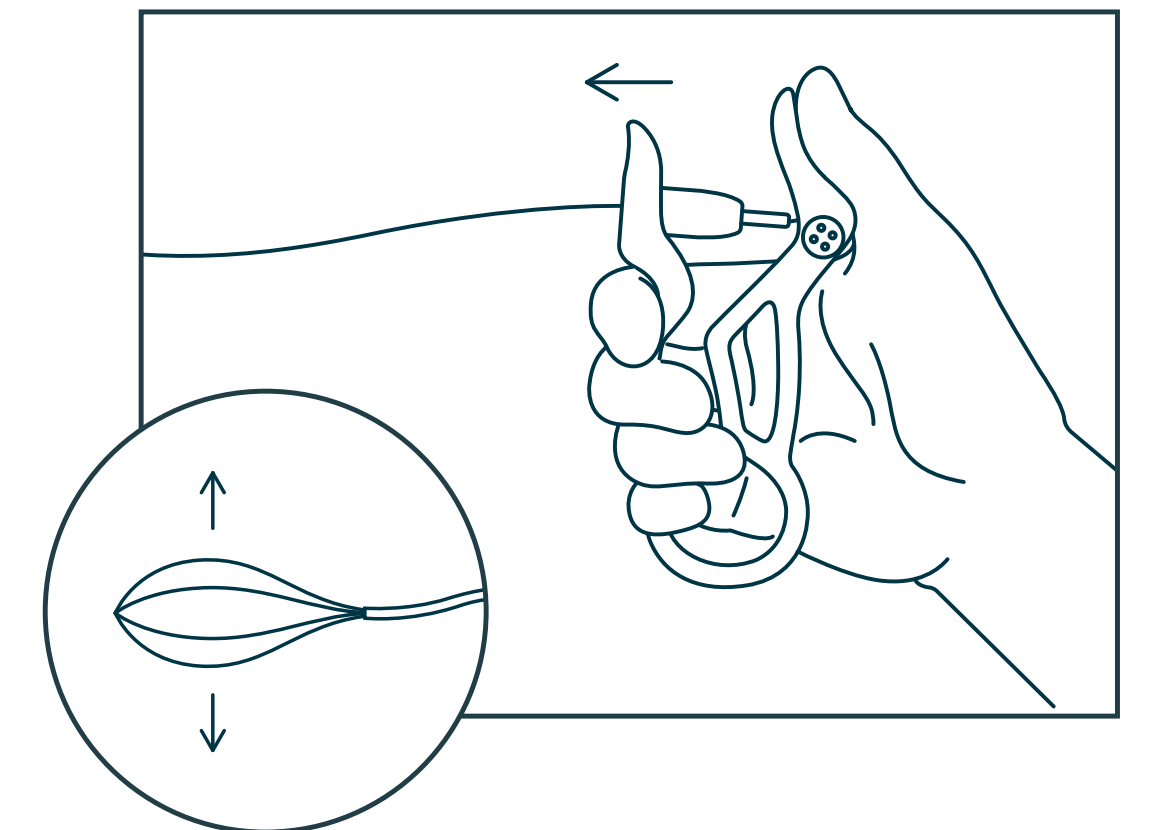
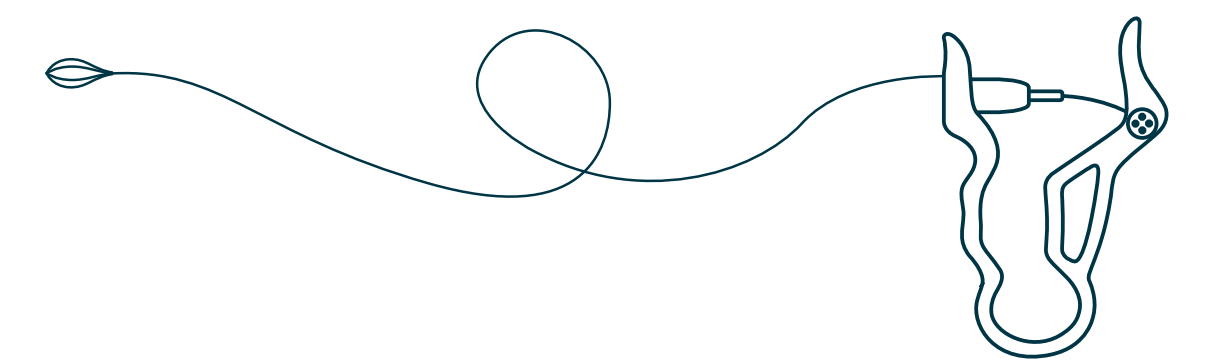
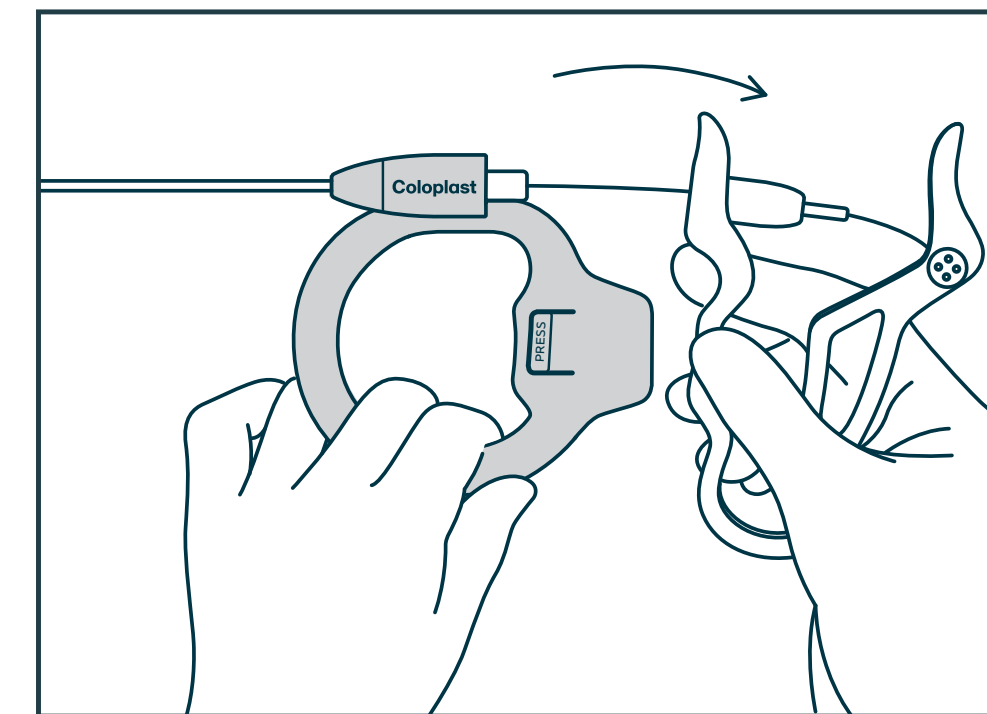
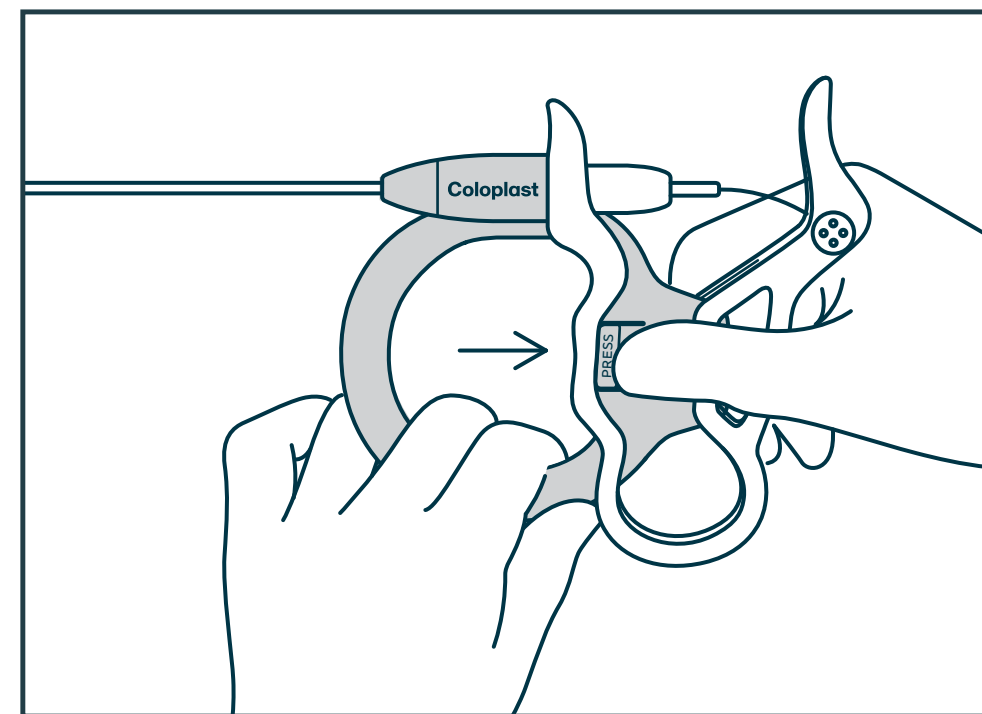
Reversibility

Quick and easy switch

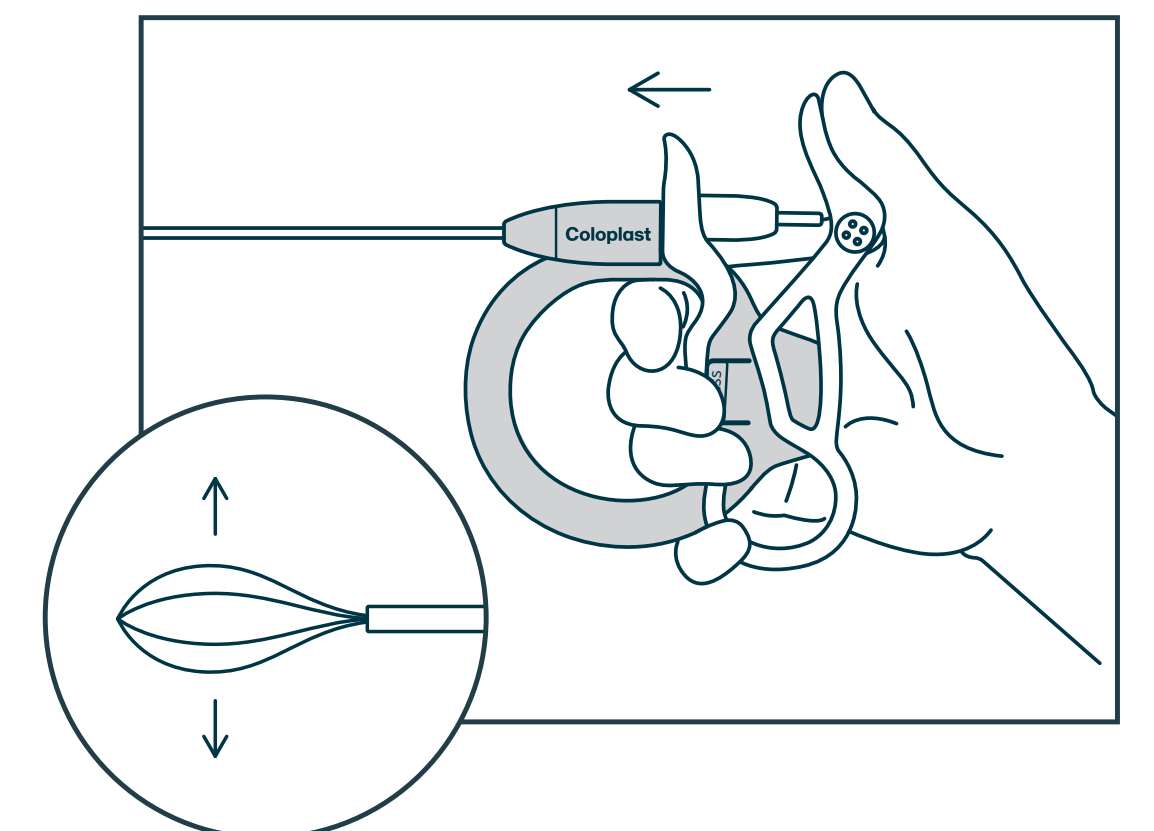
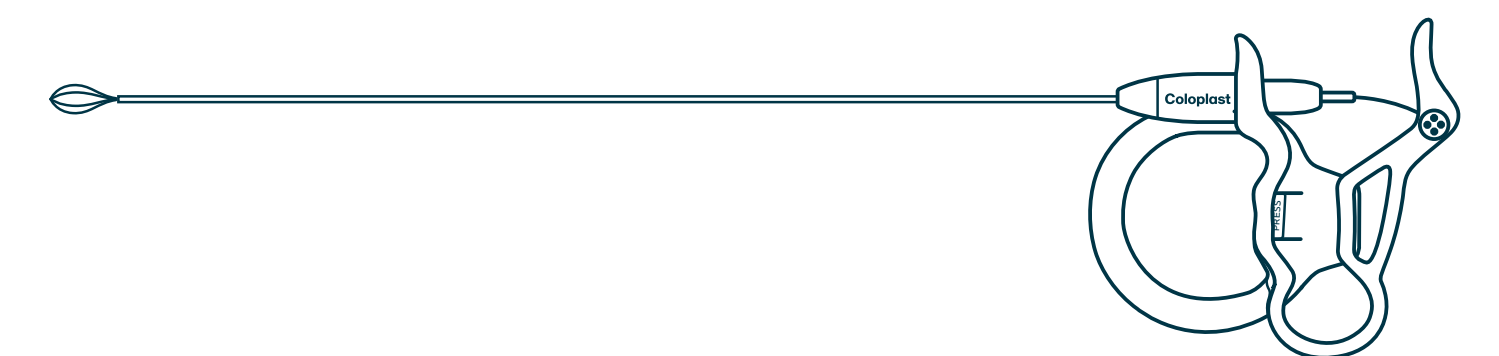
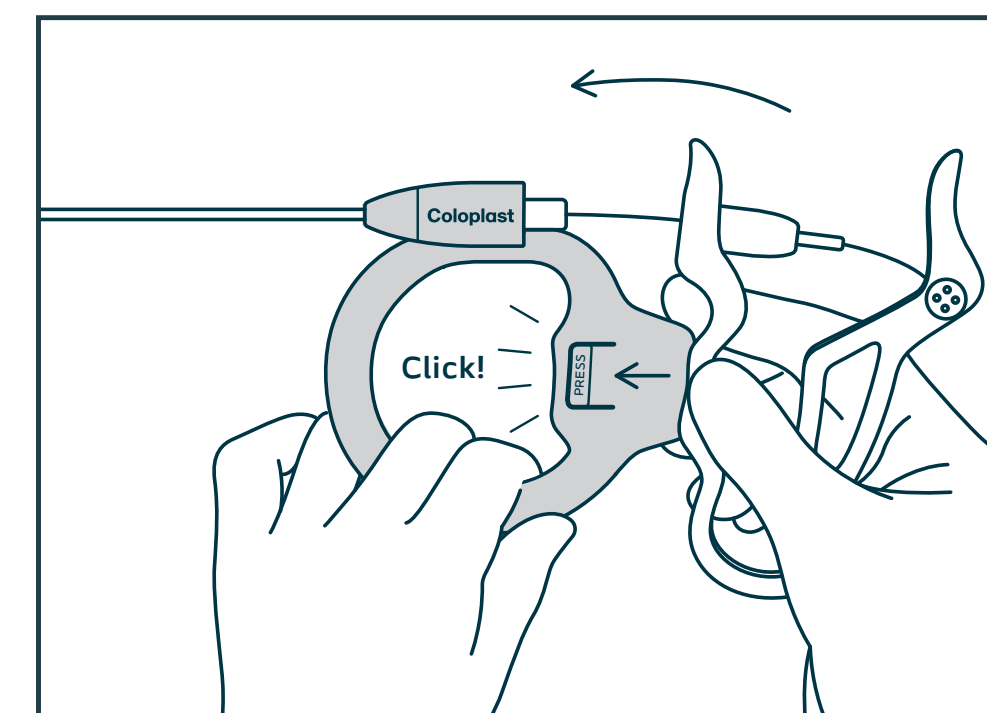
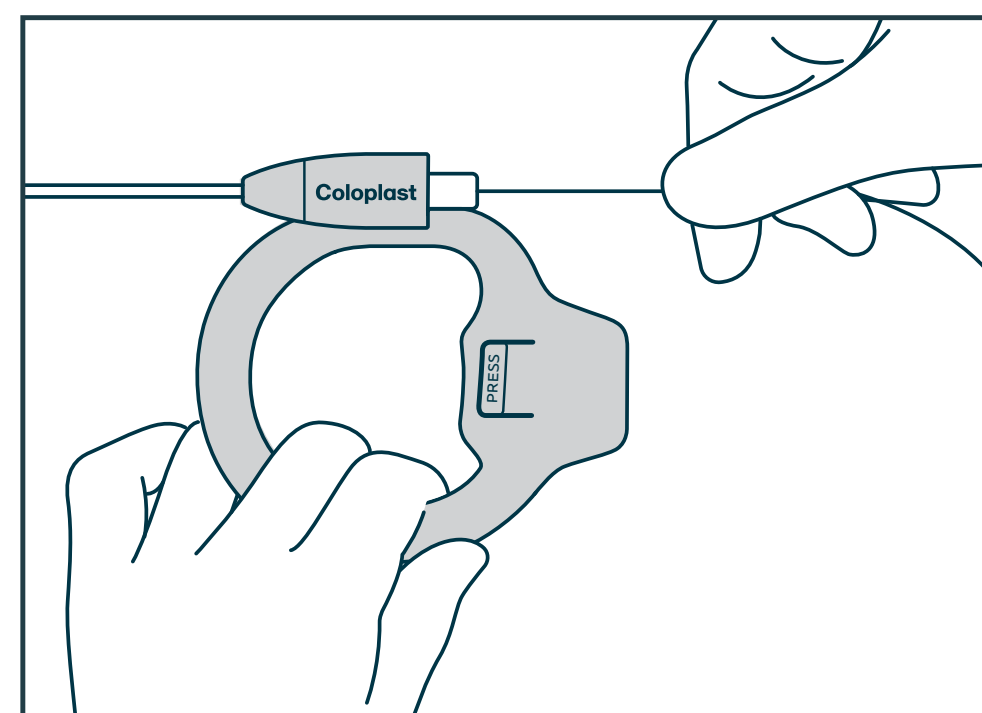
From **rigid** to **flexible** configuration

From **flexible** to **rigid** configuration

From **rigid** to *flexible*





From *flexible* to **rigid**



Product details

Dormia® DualPerc PCNL Basket

Item	Description	Rigid Shaft Length	Rigid Shaft Diameter	Flexible Shaft Length	Flexible Shaft Diameter	Basket Size
 EXP448	Dormia DualPerc Stone Extractor 4.8Fr	35 cm	4.8Fr	64 cm	3Fr	12.5 mm
 EXP470	Dormia DualPerc Stone Extractor 7Fr	35 cm	7Fr	64 cm	3Fr	12.5 mm

DORMIA® DUALPERC BRIEF STATEMENT

Intended Use

Dormia DualPerc is intended to be used for extraction of stones in the kidney and bladder.

Intended Medical Indication

Dormia DualPerc is an interventional endourological device used to remove stones and stone debris following lithotripsy, located in kidney (calix, pelvis, ureteropelvic junction...) through antegrade percutaneous access or in the bladder through retrograde natural access.

Contraindications

Contraindications to the medical device

The device is not intended for use other than for endourological procedure. Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient. The device contains nitinol materials. Do not use in case of patient's known allergy to device materials.

Contraindications to the endourological procedure

Untreated urinary tract infection. Uncontrolled haemostasis disorder. Malignant kidney or urinary tract tumor. Percutaneous NephroLithotomy (PCNL) procedure is not indicated in:

- Pregnancy unless exceptional situation
- Bleeding disorders

Warnings and Precautions

This device must only be used by trained and experienced physicians. Physicians must inform patients of the possible undesirable side effects.

Potential Complications

Adverse events involving patients have been reported, which may be related to the procedures used or problems occurring with the device (such as detachment of a part of the device, breakage, or inability to withdraw the basket), especially if the operating procedure and the warnings above are not observed, although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: Tissue trauma (mucosal abrasion, perforation), infection (e.g. urinary tract infection, pyelonephritis, severe infection...), pain, bleeding, haematuria, foreign object in body, device embedded in tissue, prolonged procedure and stone impaction.

Advice to the Patient

The patients should be educated about their interventional procedure. The patients should be advised in terms that they understand to inform the attending physician immediately if any abnormality or adverse event occurs (as haematuria, infection, pain).

The risks and benefits of using Dormia® DualPerc should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

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

Minneapolis, MN PM-28278