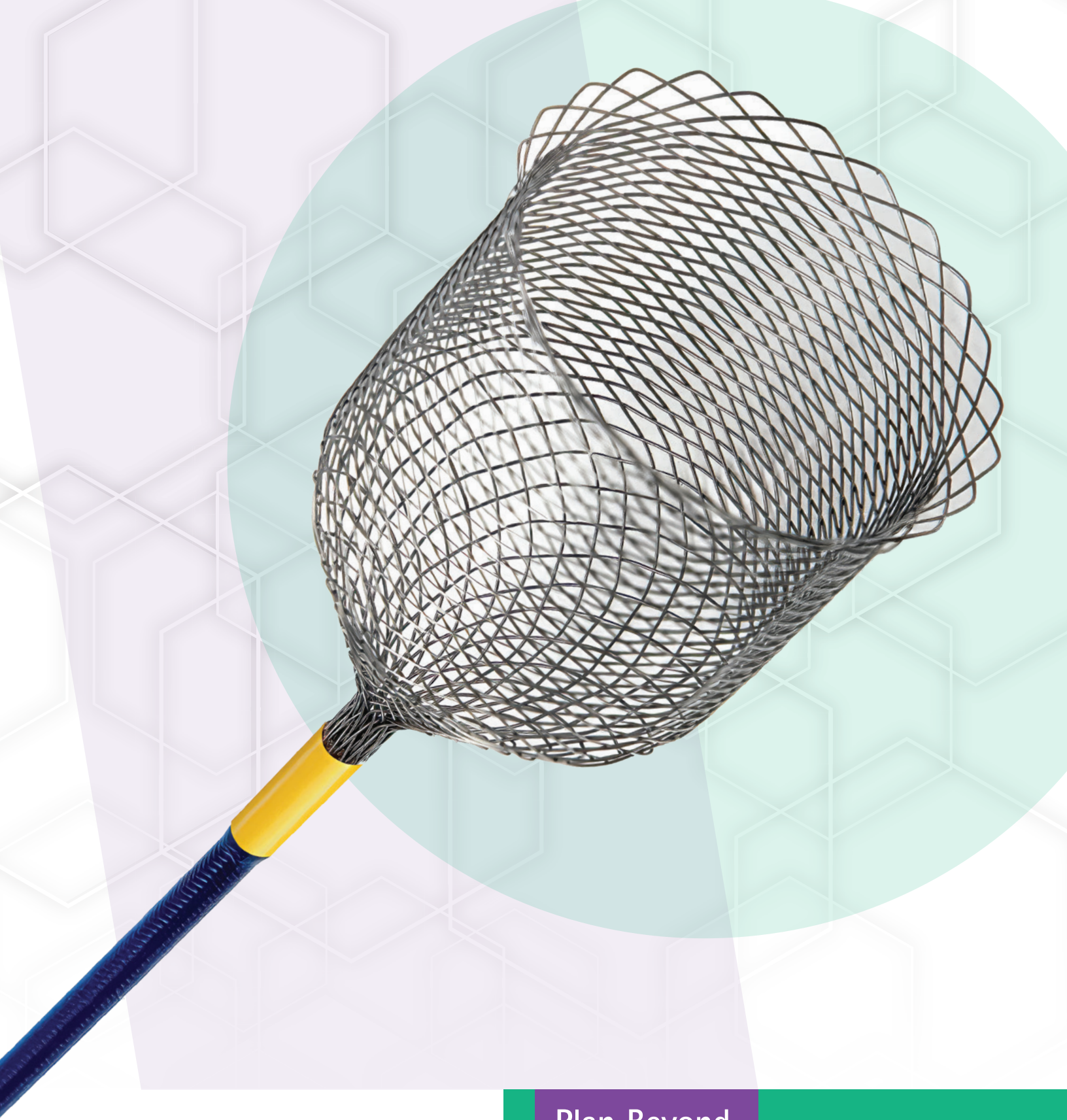


Plan Beyond.

ŌNŌ® Retrieval Device

Transcatheter Foreign Object Retrieval

Interventional Systems
B BRAUN
SHARING EXPERTISE

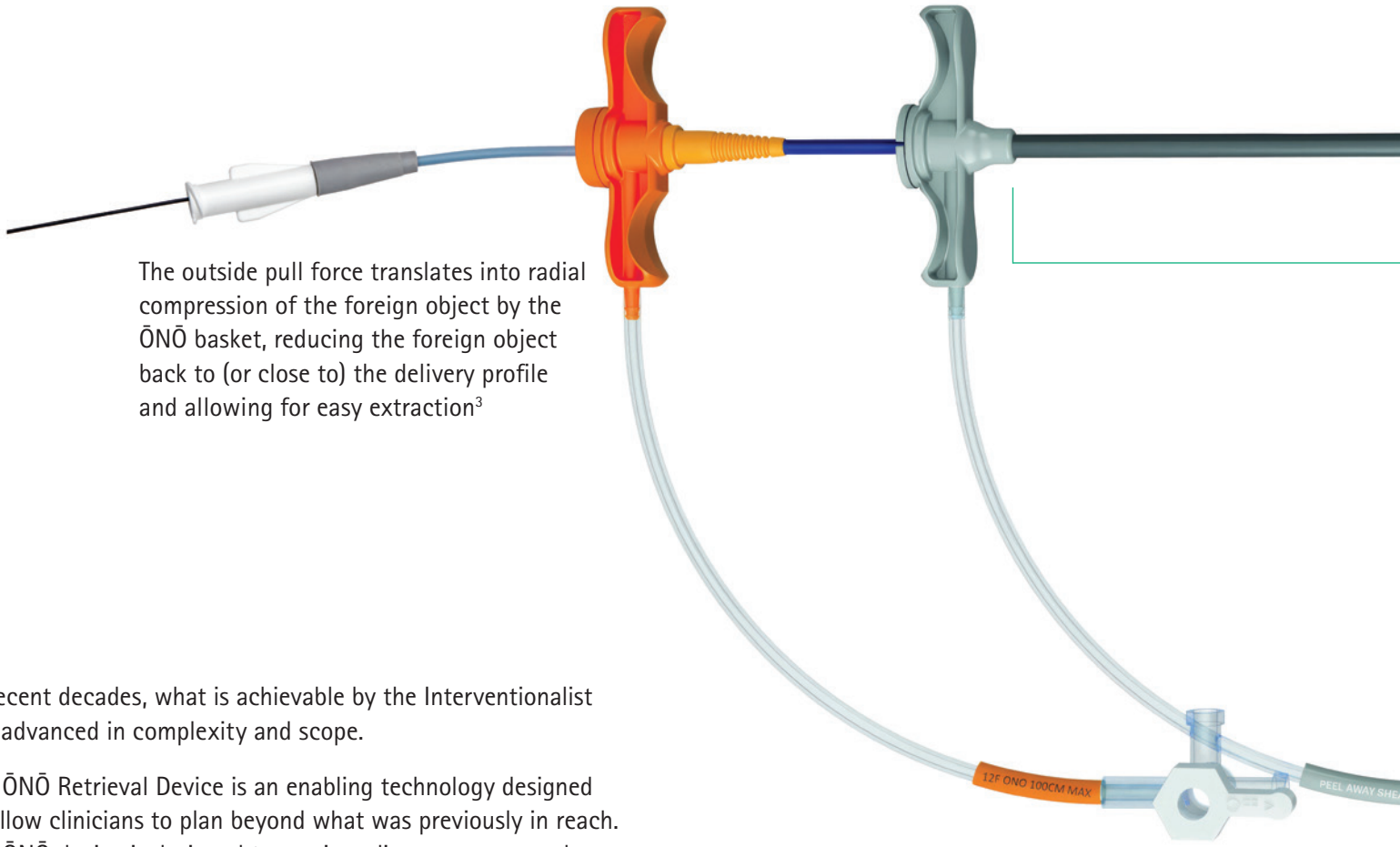
ŌNŌCOR
Advancing Safety First

ŌNŌ® Retrieval Device: Key Attributes

The ŌNŌ Retrieval Device is designed to receive, align, compress and remove material from the vascular system, allowing clinicians to retrieve what previously may not have been in reach.[1; 2]

Designed to utilize the existing access site

Indicated for use in the cardiovascular system to retrieve foreign objects using minimally invasive surgical procedures[2]



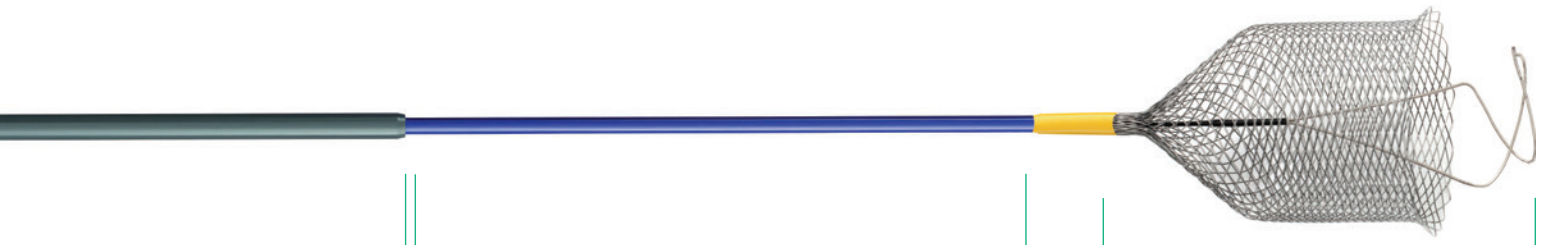
The outside pull force translates into radial compression of the foreign object by the ŌNŌ basket, reducing the foreign object back to (or close to) the delivery profile and allowing for easy extraction[3]

In recent decades, what is achievable by the Interventionalist has advanced in complexity and scope.

The ŌNŌ Retrieval Device is an enabling technology designed to allow clinicians to plan beyond what was previously in reach. The ŌNŌ device is designed to receive, align, compress and remove material from the vascular system. It is compatible with commercially available vascular sheaths, endovascular snares and other graspers.

On the creative medical frontier, the ŌNŌ device is a must-have tool, complementing your skillset.

Receive. Align. Compress. Remove.



Tear-away sheath allows introduction into any retrieval sheath 12 F or greater (maximum 75 cm overall length)

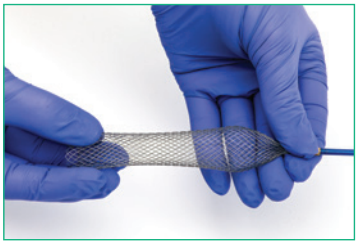
Flexible trackable catheter with 7 F compatible lumen or smaller (minimum 100 cm length)

Proprietary 35 mm basket flare* compatible with vessels as small as 10 mm

Facilitates coaxial alignment of the object for streamlined capture into the retrieval sheath[1]

Designed to enhance snaring capability and allows large device retrieval through a smaller sheath compared to snaring alone[1]

Designed to allow unobstructed blood flow when deployed



* Note: Diameter of the basket barrel is 30 mm. Full diameter including the basket flare is 35 mm. Snare is not included.

Introduction and Burden

Intravascular or intracardiac foreign bodies, although rare, can cause severe morbidity.[4]

The continued advancement of medical technology
has led to the expansion of intravascular and intracardiac devices to treat a wide range of cardiovascular conditions.[5; 6]

These include structural heart devices
(atrial septal defect [ASD] closure, left atrial appendage closure [LAA] devices, valves etc.), leadless pacemakers, coils, clips, balloons, guidewires, catheters, filters, and more.[4; 5; 7]

As the use of these devices has increased,
so have the reports of complications such as device migration or embolization.[8; 9]

Although some patients may be asymptomatic,
clinical signs can include arrhythmia, pulmonary symptoms, cardiogenic shock, and sudden cardiac arrest.[7; 10]

Embolized devices or endovascular foreign bodies
often require urgent removal, using **surgical or percutaneous techniques.**[4; 5; 7]

Device migration or embolization
can be immediate, taking place during the implantation procedure, or delayed, occurring within the hours, weeks, or sometimes months following the procedure.[7; 11]

While uncommon, these events can be potentially life-threatening,

particularly if localized to the heart or great vessels.[7]

Balloons are often used in endovascular procedures

and can rupture which may lead to fragmentation and embolization.[24; 25]

The incidence of balloon rupture is estimated to be between **3.6% to 10%** for balloon angioplasty,[24] and up to **33%** for balloon aortic valvuloplasty.[25] Balloon rupture does not necessarily lead to fragment embolization.

Reports have generally estimated the incidence of intravascular foreign body mispositioning or embolization to be around 0.1%–0.9%.[4]

However, rates may vary depending on the specific device, patient population, and procedure being conducted.

Device	Reported Device Embolization Migration or Dislodgement Rates*
Transcatheter edge-to-edge repair (TEER)/Clips	**0.1%**[12; 13]
ASD Closure Devices	**0.1%–1.3%**[7; 14; 15]
LAA Closure Devices	**0%–2%**[7; 16; 17]
Venous Stents	**0.17%–4.3%**[18; 19]
Leadless Pacemakers	**0.13%–0.76%**[20-23]

**** Rates may vary depending on the specific device, patient population, and procedure.***

Cardiac tumors and intravascular thrombi may migrate or localize in the heart requiring retrieval and removal.[26-28]

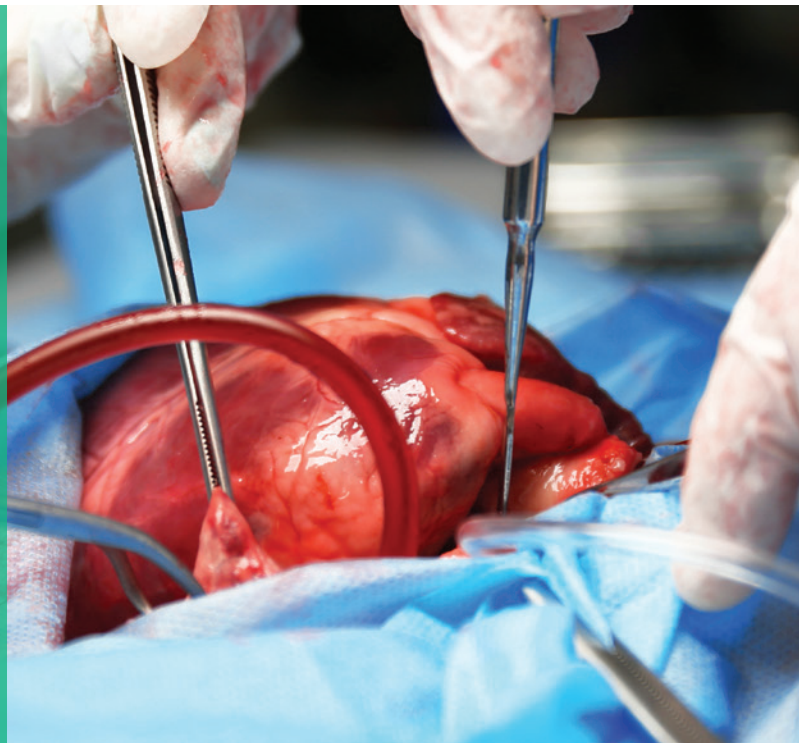
Intracardiac and intravascular thrombi are associated with significant morbidity and mortality.[29; 30]

- Widely used management strategies include anticoagulation therapy, systemic thrombolysis, and surgical embolectomy.[31]
- Thrombi that are older, more organized and fibrin-rich often exhibit increased resistance to thrombolysis compared to acute red blood cell-rich thrombi.[32; 33]
- In patients with catheter-related right atrial thrombi, primary anticoagulation and thrombolysis treatment fails in approximately 27.3% and 33.3% of cases, respectively.[34]

Cardiac tumors or masses occur rarely.[35]

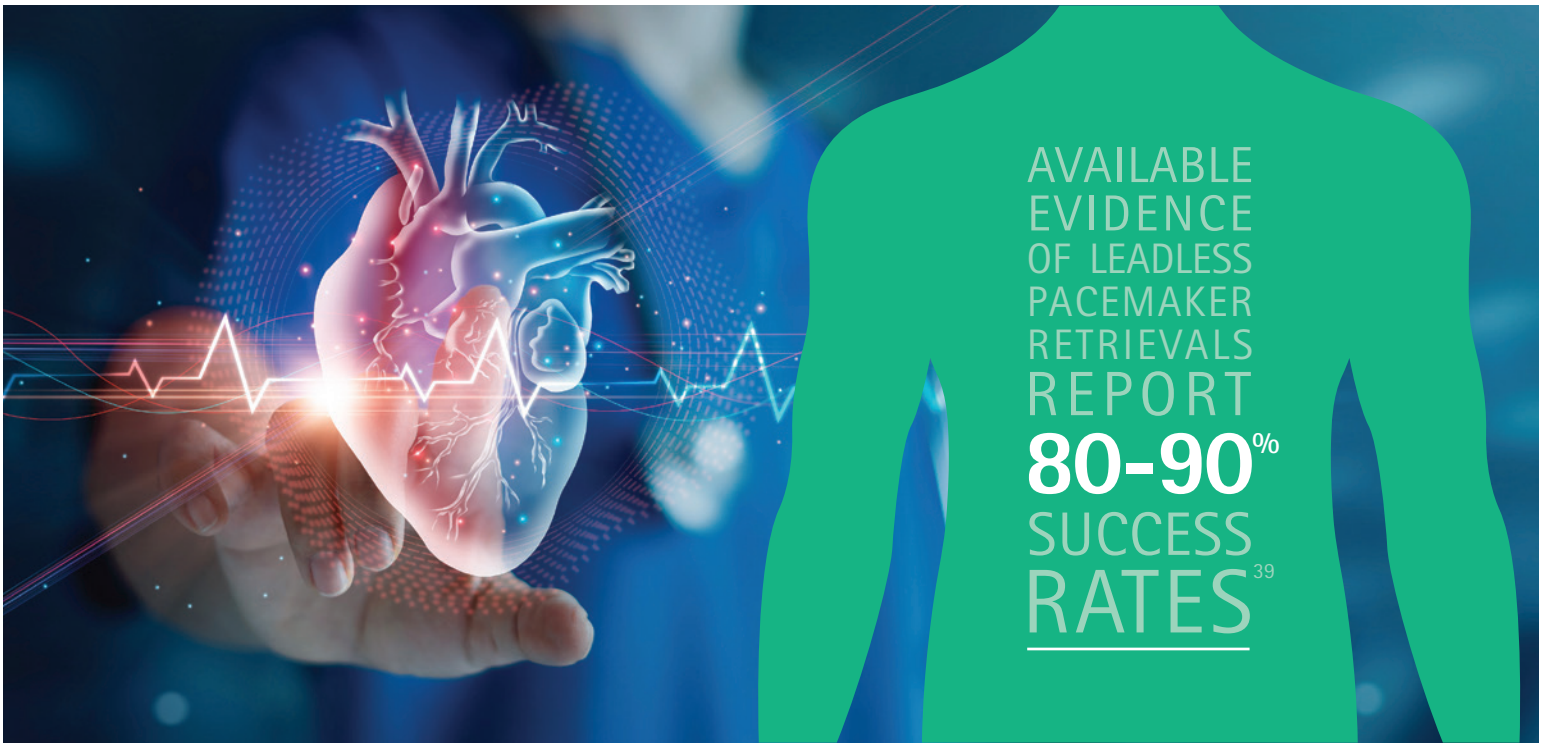
- Primary cardiac tumors have an incidence of 0.002% to 0.3% based on an autopsy series.[36]
- The incidence of patients clinically diagnosed with a primary cardiac tumors, however, is estimated at 1,380 per 100 million individuals, suggesting that many go undiagnosed.[35]
- Secondary cardiac tumors or cardiac metastases are approximately 22 to 132 times more common than primary cardiac tumors.[35]
- Surgical resection of cardiac tumors is traditionally conducted via open median sternotomy.[37]

Recent reports have suggested that some cardiac tumors and intravascular thrombi can be successfully removed using less invasive or endovascular methods.[27-29; 37]



Intracardiac devices such as leadless pacemakers may undergo planned retrieval and removal due to device malfunction or end of life.[38; 39]

- The battery life of a leadless pacemaker is between 4.7 to 15 years depending on pacing thresholds. Given this, some patients may require the implantation of multiple devices throughout their lifetime.[39]
- Simply abandoning the previous leadless pacemaker and implanting a new device may lead to compromised cardiac function, device-device interference, or other potential long-term adverse events.[38; 39]
- Retrieving and removing the leadless pacemaker when possible, prior to implanting a new device would avoid these potential complications and reduce the amount of nonfunctional cardiac hardware present.[38; 39]
- Successful and safe percutaneous removal of leadless pacemakers 4 to 5 years after implantation have been reported, indicating that removal may remain feasible at later time points, such as at device end of life.[40]



Clinical Value

The ŌNŌ Retrieval Device provides an **effective percutaneous solution** to retrieve objects from the cardiovascular system, avoiding the need for invasive open surgical removal procedures.[41]

The ŌNŌ Retrieval Device facilitates

percutaneous cardiac tumor removal before symptoms or complications develop, in patients where surgical resection is not yet indicated.[3]

Failure to remove intravascular foreign bodies percutaneously

may require revision to emergent surgical removal.[4; 7; 42]

Surgical structural heart procedures

are associated with higher in-hospital mortality, greater complication risk, and longer length of hospital stay compared to transcatheter procedures.[43; 44]

Emergency open surgical procedures due to transcatheter device complications

exhibit greater mortality than primary surgical structural heart procedures alone.[45-47]

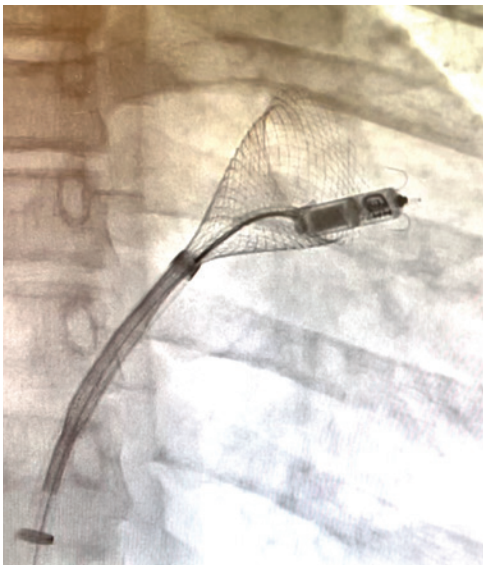
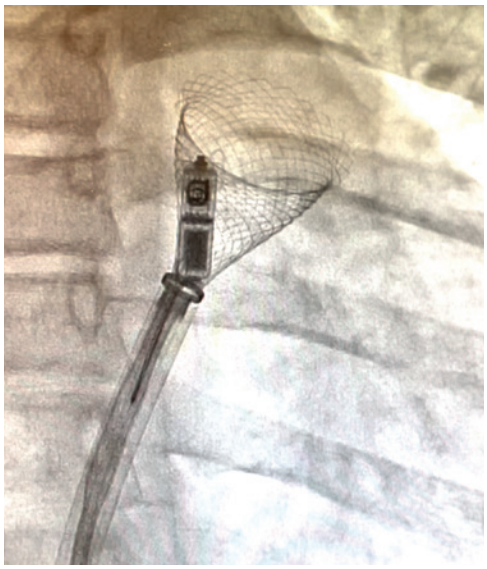
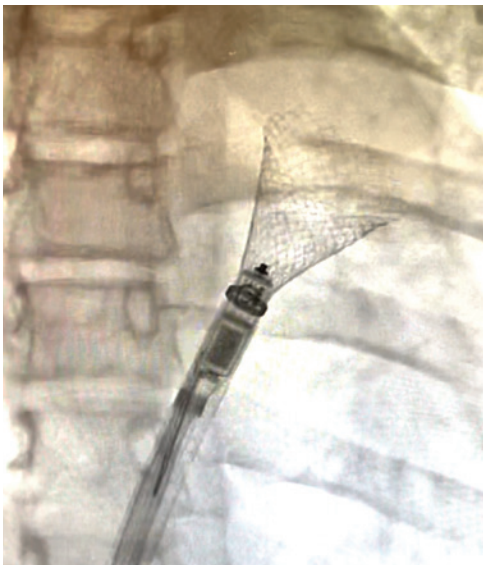
The ŌNŌ Retrieval Device can be used to facilitate the capture and removal of a wide variety of intravascular foreign bodies with a high rate of clinical success, exhibiting considerable **versatility and reliability.**[41; 48]

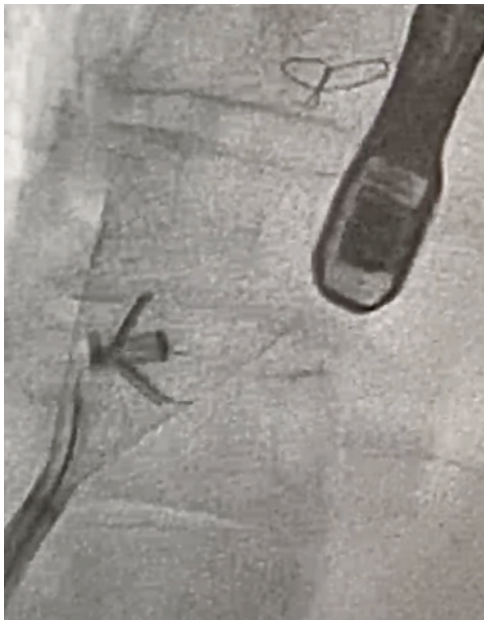
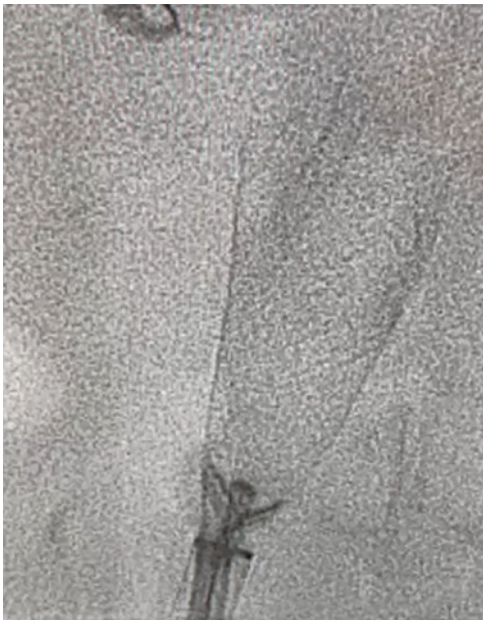
Intracardiac and intravascular thrombi are associated with significant morbidity and mortality.[29; 30]

- The ŌNŌ Retrieval Device has been successfully used to retrieve atrial tumors, cardiac thrombi, ruptured balloons and associated fragments, leadless pacemakers, stents, clips, ASD devices, LAA devices, and more.[11; 26-28; 48-51]
- A wide variety of other devices or objects may also be suitable for retrieval with the ŌNŌ Retrieval Device, including but not limited to ventricular septal defect (VSD) devices, patent ductus arteriosus (PDA) devices and other malpositioned or embolized occlusion devices, guidewires, catheter fragments, coils and more.[41]
- In addition to migrated or embolized foreign bodies, the ŌNŌ Retrieval Device may also be used to facilitate the removal of malfunctioning or non-functioning devices, including those at end of life such as leadless pacemakers.[39; 41; 52]
- The ŌNŌ Retrieval Device is suitable for use during both emergency and planned intravascular retrieval procedures.[4]
- The ŌNŌ Retrieval Device has been successfully deployed in 100% of clinical cases to date.[48]
  - Unsuccessful retrieval procedures were complicated by factors such as catheter sheath length, snare or grasper capture, and/or patient characteristics. [1]

The ŌNŌ® Retrieval Device simplifies complex intravascular foreign body retrieval procedures and can easily be integrated into an interventional cardiologists' practice.[3; 41]

- The ŌNŌ Retrieval Device assists with proper orientation or alignment of the object for appropriate capture and removal, such as with leadless pacemakers and clips where coaxial orientation within the sheath is required for removal.[11; 51]
- The ŌNŌ Retrieval Device compresses the captured item, facilitating the potential removal of larger foreign bodies, or the use of smaller catheter sheaths.[27; 41]
- Once the item is captured, the ŌNŌ Retrieval Device covers or shields it from critical surrounding cardiac or vascular structures, such as cardiac valves, protecting against potential trauma or damage.[11; 50]
- The nitinol ŌNŌ basket is easily collapsed and redeployed during the procedure to optimize basket size, engagement angle, device alignment, or to withdraw the object to a safer location where appropriate alignment and compression for removal can take place without risk to critical structures.[11; 50]
- The ŌNŌ Retrieval Device is compatible with a variety of commercially available vascular sheaths, endovascular snares, and other graspers, with no other specific accompanying equipment required, allowing clinicians continued use of their preferred retrieval tools.[1; 3]
- Minimal training is likely required to use the ŌNŌ Retrieval Device, especially for clinicians familiar with catheter-based therapies.[3] Continued expert teleconferencing or in-person support on use of the device is available to clinicians as needed.

The ŌNŌ Retrieval Device coaxially aligns the object for easy extraction from the body. Images provided by Onocor LLC.

Resource Use and Economic Value of the ŌNŌ® Retrieval Device

Percutaneous foreign body removal procedures using the ŌNŌ Retrieval Device may shorten procedure time compared to open surgical procedures.

A case report

of percutaneous resection of an atrial tumor using electrosurgery and the ŌNŌ Retrieval Device had a recorded procedure time of **43 minutes.**[28]

The average operation time

for surgical cardiac tumor removal is **198 minutes.**[53]

Endovascular foreign body removal procedure time

is estimated to range from **6 to 208 minutes.**[5; 54]

The mean procedure time

of mitral valve surgery via conventional midline sternotomy is **210.7 minutes.**[55]

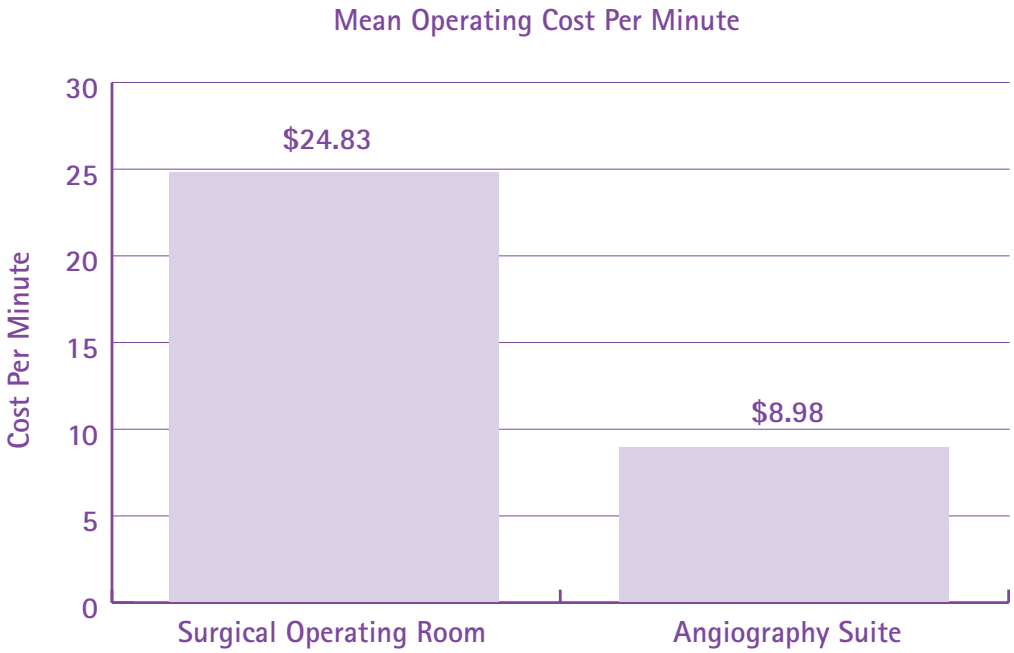
TAVR and PCI procedures

require on average less time compared to SAVR and CABG procedures **(54.6 minutes vs. 239.7 minutes).**[56]

Improving endovascular foreign body retrieval with the ŌNŌ device may reduce costs by avoiding planned and emergency open surgical procedures.

Percutaneous procedures on average incur lower operating time per minute costs than surgical procedures.[57; 58]

- Mean surgical operating room time cost is approximately **$24.83 per minute** in the Americas.[57]
- The cost to operate an angiography suite is estimated at **$539 per hour, or $8.98 per minute.**[58]



- Surgical ASD closure procedures are estimated to incur higher total costs than transcatheter ASD device closures **(2012 USD $60,992 vs. $55,841).** Transcatheter ASD procedures are associated with lower costs for medication, follow-up radiologic and laboratory testing, and a shorter length of stay.[59]
- Index hospital costs are estimated to be significantly lower for transcatheter aortic valve replacements compared to surgical aortic valve replacements, across all patient mortality risk groups **(2016–2018; low: $61,845 vs. $68,986; intermediate: $64,658 vs. $76,965; high: $65,594 vs. $91,005).**[60]
  - Cost savings were primarily driven by significantly shorter length of stay, which was on average 5 to 8 days shorter across mortality risk groups, for TAVR patients compared to SAVR patients.[60]
- Emergency cardiac procedures can cost approximately **17% to 30% more** than elective procedures.[61]

Clinical Evidence

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For complete list of clinical evidence, visit our website.

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