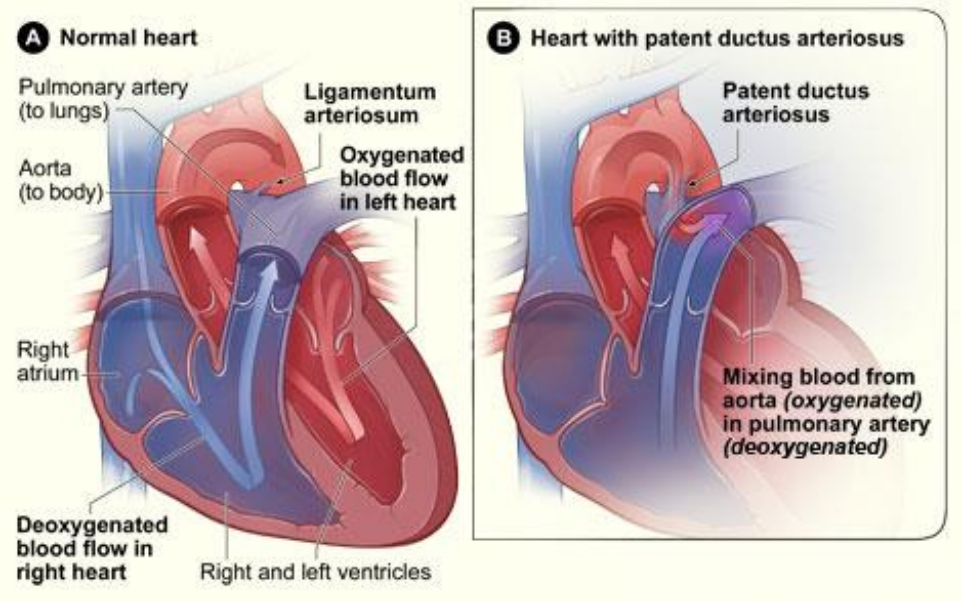
Perfecting Performance

Occlutech®

Patent Ductus Arteriosus Occluder

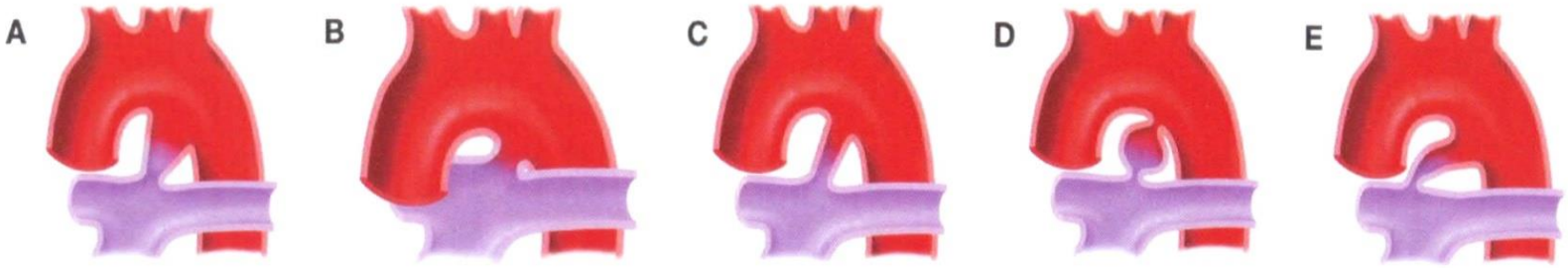
Patent Ductus Arteriosus (PDA)

PDA Anatomy



- The PDA is a congenital heart defect where a neonate's ductus arteriosus fails to close after birth.
- Symptoms are uncommon but in the first year of life increased work of breathing and poor weight gain are observed
- PDA may lead to congestive heart failure if not closed in the later years

PDA Morphology



Type A (“conical”) ductus, with well-defined aortic ampulla and constriction near the pulmonary artery end.

Type B (“window”) ductus, with very short length.

Type C (“tubular”) ductus, which is without constrictions.

Type D (“complex”) ductus, which has multiple constrictions.

Type E (“elongated”) ductus, with the constriction remote from the anterior edge of the trachea.

PDA type	Relative incidence
Type A	64,6%
Type B	17,7%
Type C	7,6%
Type D	3,8%
Type E	6,3%

PDA Epidemiology

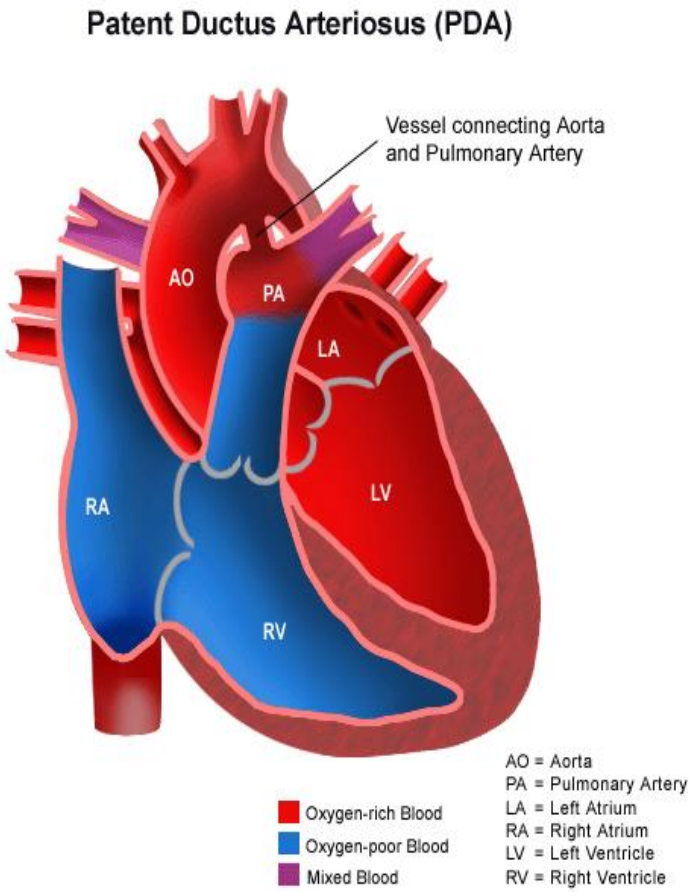
- Incidence
  - 5-10% of all congenital heart defects
  - 1-2 in 1000 birth

- Mortality
  - The rate in adults with untreated PDA is estimated to be 1.8% per year

- Clinical Indication
  - The Occlutech® PDA Occluder is an occlusion system, which is percutaneously implanted through a catheter intervention technique and intended for the non-surgical occlusion of Patent Ductus Arteriosus (PDA).

Causes and Symptoms

- Causes
  - Cause of patent ductus arteriosus isn't known
  - Genetics play a role in causing the condition. A defect in one or more genes might prevent closing of the ductus arteriosus after birth.
- Symptoms
  - Poor eating, which leads to poor growth
  - Sweating with crying or eating
  - Persistent fast breathing or breathlessness
  - Easy tiring
  - Rapid heart rate



PDA Treatment Options

- Medicines
  - Helps closure PDAs in premature infants

- Surgery
  - A premature or full-term infant has health problems due to a PDA and is too small to have a catheter-based procedure
  - A catheter-based procedure doesn't successfully close the PDA
  - Surgery is planned for treatment of related congenital heart defects

- Catheter based approach
  - Gold therapy
  - Quick recovery
  - Rare complications

Implantation

Anterograde approach

- Preliminary examinations such as medical history, echo and lab tests
- Catheterization placing Pigtail catheter via veneous approach through the femoral vein or femoral artery.
  Defect sizing
- Crossing the ductus antegradely from the veneous system and placing MP catheter in the dAo.
  Exchanging with stiff guidewire and advancing of delivery sheath
- Connection to the pusher and retraction of the occluder inside the loader
- Positioning of the occluder
- Release of the occluder

Occlutech® Patent Ductus Arteriosus (PDA) Occluder

Occlutech PDA Occluder Family

- PDA occluder
  - Regular
    - Standard Shank
    - Long Shank
  - Hubless
    - Standard Shank
    - Long Shank

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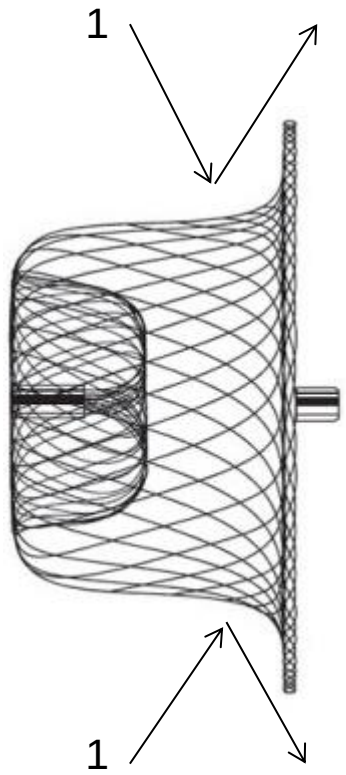
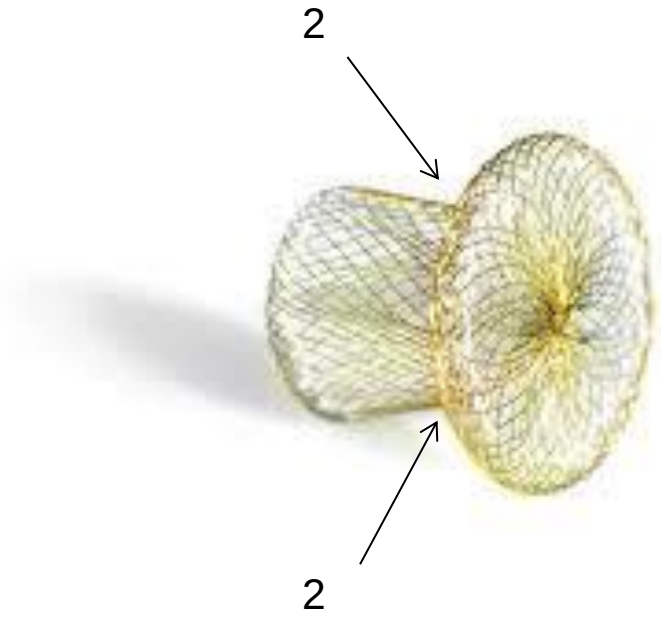
Features&Benefits

Nitinol Brading	Flexibility and superior adaptability
Titanium oxide layer	Corrosion resistance, less nickel leaching
Polyester patches	Rapid sealing
Low aortic profile	Avoids obstruction to aorta
No distal clamp force	Reduces thrombus risk
Inverted shank	Good option for patients with PDA and PAH No hub in the aortic disk
Protruding hub	Easy recapture
Larger pulmonary end	Provides good anchoring and stability

Pulmonary Hypertensive Ducts





1. Pinched waist configured in duct wants to retake original form and may fall out into the aorta

2. Pre-waisted design means device will remain in the duct due to pulmonary stability

Occlutech Hubless PDA

- Benefits
  - Universal Occlutech ball-pusher machanism.
  - Safer device release and no «jumping» feeling from the pusher
  - More flexibility to implant the occluder in different angles
  - Longer ball length (2 mm) to recapture the device easily when needed

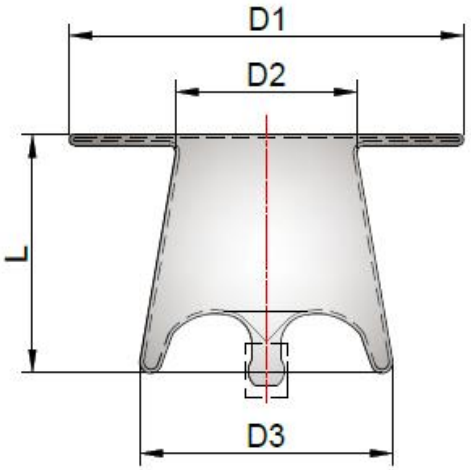
Compatibility Chart

Standard PDA

Occlutech® PDA Occluder Article No	Ø D1 [mm]	Ø D2 [mm]	Ø D3 [mm]	Length L [mm]	Occlutech® Delivery Set (ODS) size [F]
42PDA05/92PDA05	9	3.5	5	4.25	6
42PDA06/92PDA05	10	4	6	5.00	6
42PDA07/92PDA05	11	5	7	6.05	6
42PDA08/92PDA05	13	6	8	6.30	6
42PDA10/92PDA05	16	8	10	7.00	7
42PDA12/92PDA05	18	10	12	12.00	7
42PDA15/92PDA05	20	12	15	14.00	8
42PDA18/92PDA05	24	14	18	16.00	9

Long shank PDA

Occlutech® PDA Occluder Article No	Ø D1 [mm]	Ø D2 [mm]	Ø D3 [mm]	Length L [mm]	Occlutech® Delivery Set (ODS) size [F]
43PDA05L/93PDA05L	9	3.5	5	7.00	6
43PDA06L/93PDA06L	10	4	6	7.50	6
43PDA07L/93PDA07L	11	5	7	8.50	6
43PDA08L/93PDA08L	13	6	8	9.00	6
43PDA10L/93PDA09L	16	8	10	10.50	7



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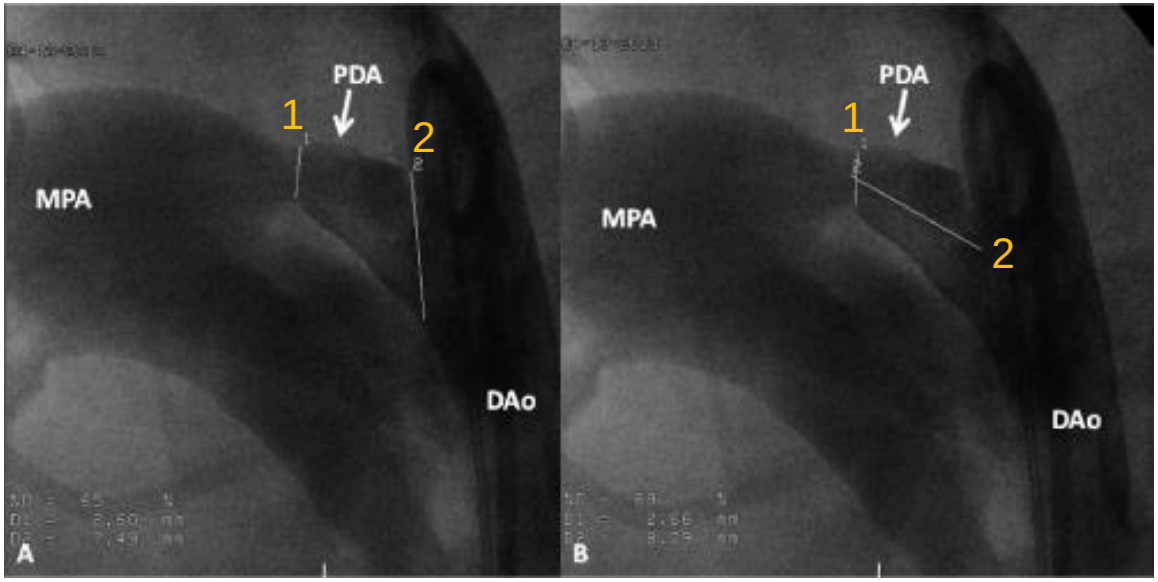
Tips&Tricks

- General
  - After loading the device to the wire pusher rotate till the end and unscrew 90 degree back
  - Check the loader to be free of bubbles
  - The implantation should be performed only from pulmonary artery side
- Sizing
  - Occlutech® PDA should be selected by the smallest measured diameter of ductus
  - Choose a device 1-2 mm larger than the minimum ductus diameter of the defect
  - Choose a device with a standard shank or long shank according to ductus length measured

Size Selection



A B

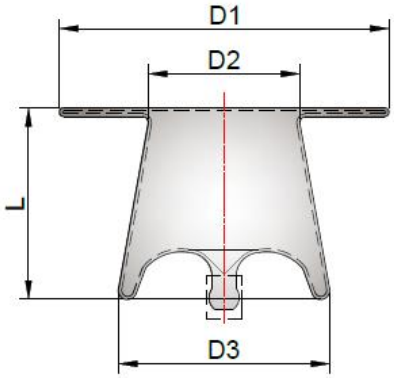


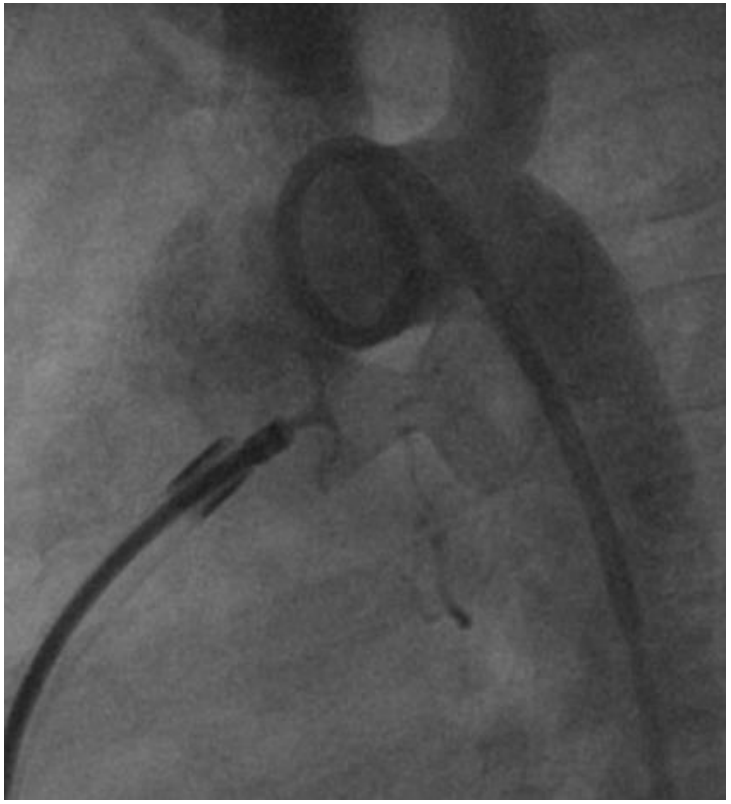
Image A. 1 - smallest diameter of the duct, **2** - ampulla size

Add 2 mm to smallest diameter and size from D2 measurement (sizing chart)

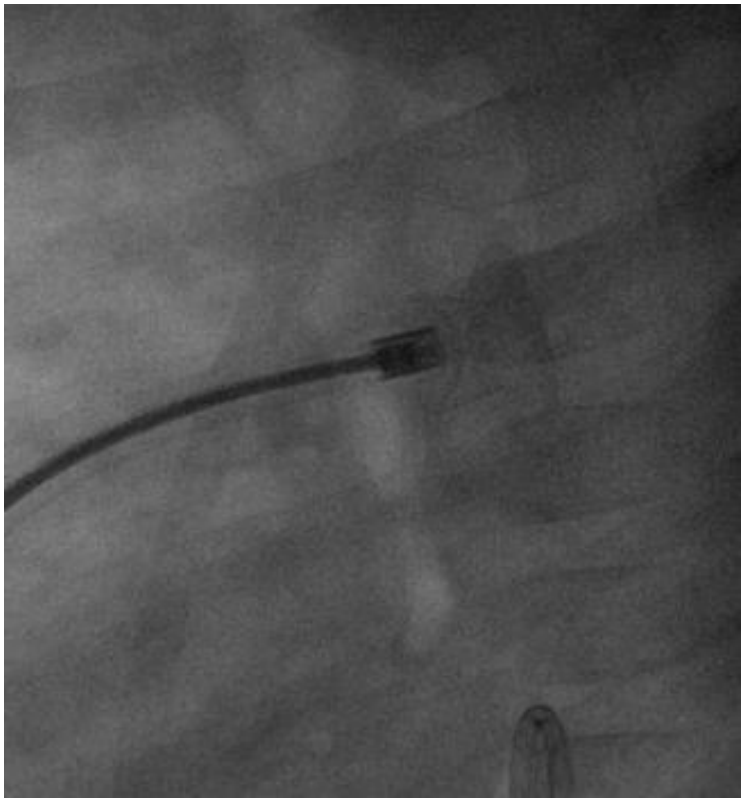
Image B. 1 - smallest diameter of duct, **2** - length of duct

When length of duct in >5mm than length of shank (sizing chart), upsize to Long Shank occluder

Case Study



Incomplete expansion of the waist of the occluder when the aortic retention disc had been pulled firmly into the ductal ampulla



Complete expansion of the occluder unsheathed in descending aorta

Case Study, Con’t

Correct configuration of the occluder following deployment with only gentle traction on the retention disc

Occlutech® PDA Occluder Clinical

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PDA Literature

The New Occlutech® PDA Occluder: Initial Human Experience

M. A. Elbashier Abdelbasit,[1*] MBBS, MD, Mazeni Alwi,[1] MBBS, MRCP, Geetha Kandavello,[1] MBBS, MRCP, Marhisham Che Mood,[1] MD, Hasri Samion,[1] MD, and Ziyad M. Hijazi,[2] MD, MPH

→ 33 pts
No MACE
Complete closure in the the follow up

The new Occlutech® patent ductus arteriosus occluder: Single centre experience

Le nouveau système d'obturation de canal artériel d'Occlutech : expérience d'un centre

Younes Boudjemline[a,b,*]

→ 35 pts

We present excellent PDA closure results using the new Occlutech® PDA occluder, similar to those achieved with competitive devices. Feasibility and safety are excellent, even in an infant population.

Is the new Occlutech duct occluder an appropriate device for transcatheter closure of patent ductus arteriosus?

François Godart[a,*], Ali Houeijeh[a], Olivia Domanski[a], Marie-Paule Guillaume[a], Mélanie Brard[b], Hugues Lucron[b]

[a] Department of Pediatric and Congenital Heart Disease, University of Lille-Nord de France, France
[b] Antilles-Guyane M3C Pediatric Cardiology Center, University Hospital of Martinique, Fort-de-France, Martinique (FWI), France

→ Very high device success (100%) rate in 42 patients
Shorter fluoroscopy time than the ADO I

The new ODO appears safe and effective in transcatheter occlusion of median-to-large ducts (up to 10 mm) with a 100% procedural success. The new device configuration with an inverted shank seems interesting with appropriate device stability, no embolization, less protrusion to the aortic or pulmonary sides, and mainly a very high rate of full occlusion in this cohort. The ODO appears already as a real alternative for transcatheter PDA occlusion among all the devices available.

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PDA Literature, Con't

Short-Term Outcomes of Patent Ductus Arteriosus Closure With New Occlutech® Duct Occluder: A Multicenter Study

REYHAN DEDEOGLU, M.D.,[1] MEKI BILICI, M.D.,[2] FIKRI DEMIR, M.D.,[2] FADLI DEMIR, M.D.,[3] ONUR ÇAĞLAR ACAR, M.D.,[4] OLGU HALLIOGLU, M.D.,[5] AYŞENUR PAC, M.D.,[6] ALEV KIZILTAS, M.D.,[7] DURAN KARABEL, M.D.,[8] SERDAR KULA, M.D.,[9] DERYA CIMEN, M.D.,[10] OSMAN BASPINAR, M.D.,[11] SEZEN UGAN ATIK, M.D.,[1] and IRFAN LEVENT SALTIK, M.D.[1]

→ 60 pts
98,2% final occlusion
No MACE

Transcatheter Closure of Patent Ductus Arteriosus in Children with the Occlutech Duct Occluder

Meki Bilici[1] · Fikri Demir[1] · Alper Akın[1] · Mehmet Türe[1] · Hasan Balık[1] · Mahir Kuyumcu[2]

→ 71 pts
Similar occlusion rates with other devices
No MACE

The results of this study showed that the Occlutech PDA occluder device is safe and effective in the closure of PDA.

The Occlutech Duct Occluder for Patent Ductus Arteriosus

A Retrospective Case Series

Najib Hanna, MD[1], Ramy Charbel, MD[2]*, Ghassan Chehab, MD[1], Bernard Gerbaka, MD[2], Zakhia Saliba, MD[1]

[1] Hotel-Dieu de France University Medical Center, Department of Pediatric Cardiology, Saint Joseph University, Naccache Boulevard, Achrafieh, Lebanon

[2] Hotel-Dieu de France University Medical Center, Department of Pediatrics, Saint Joseph University, Naccache Boulevard, Achrafieh, Lebanon

→ 18 pts
High immediate closure rate
No MACE
Good for long PDAs

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PDA Literature, Con't

The New Occlutech Duct Occluder: Immediate Results, Procedural Challenges, and Short-Term Follow-Up

Vikram Kudumula, MRCPCH; Demetris Taliotis, MRCPCH; Christopher Duke, FRCP

→

22 pts
95%procedural success
No device related complication
100% occlusion in the follow up

Patent ductus arteriosus closure using Occlutech® Duct Occluder, experience in Port Elizabeth, South Africa

Lungile Pepeta, Adele Greyling, Mahlubandile Fintan Nxele, Zongezile Masonwabe Makrexeni
Department of Paediatrics and Child Health, Division of Paediatric Cardiology, Dora Nginza Hospital, Walter Sisulu University, Port Elizabeth, South Africa

→

65 pts

Short- and medium-term results have shown that the Occlutech® Duct Occluder is a safe and effective device for closure of ducts in appropriately selected patients including patients with adequate ductal length, ductal ampulla to accommodate the aortic disk, and even patients who are <5 kg.

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