optimed

# sinus-SuperFlex-DS

## SOLUTIONS FOR THE HYPOPLASTIC LEFT HEART SYNDROME (HLHS)

arterial

4F
Ø
device

max.
.018i
guide
wire

NiTi
nitinol
stent

radioopaque
markers

anti-jump
technique

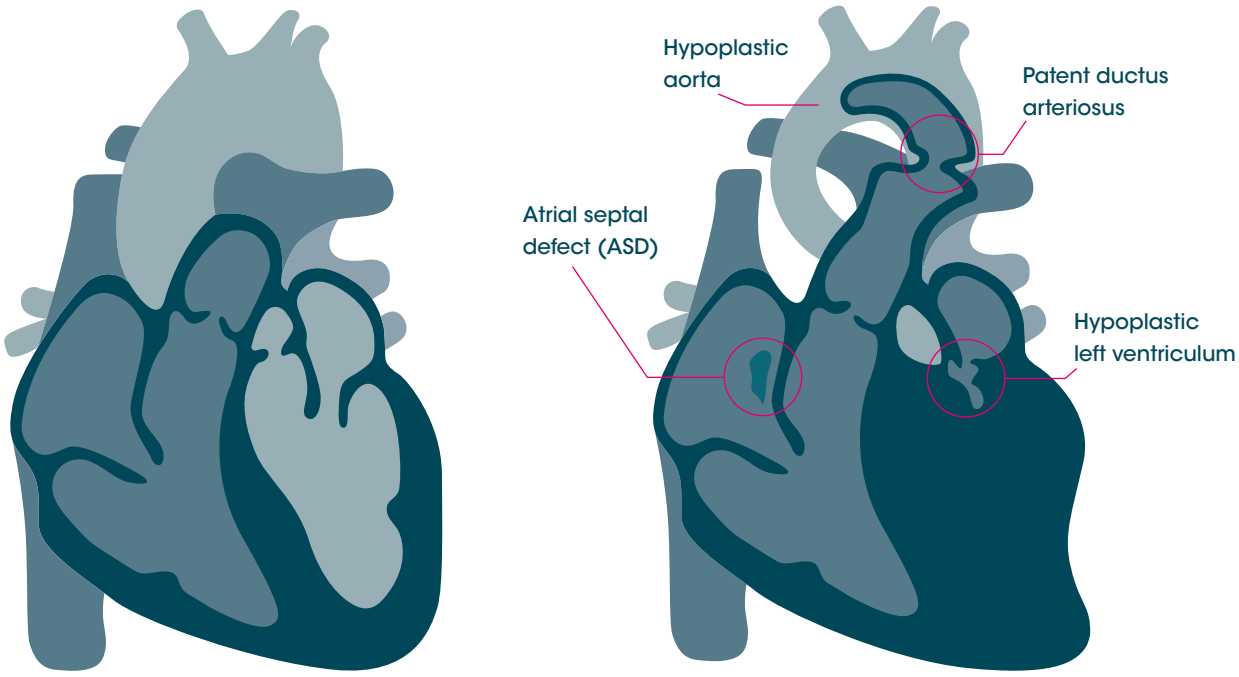
CONGENITAL HEART DISEASES

# THE HYPOPLASTIC LEFT HEART SYNDROME

sinus-SuperFlex-DS

Congenital Heart Disease (CHD) is defined as a structural abnormality of the heart and / or great vessels that is present at birth. The prevalance of CHD is around 0.8 – 1 % of all live births.[1] CHD accounts for almost 28 % of deaths from birth defects in the first month of life and approximately 50 % of the deaths during the first 12 months.[2]

# HYPOPLASTIC LEFT HEART SYNDROME




Normal heart

Hypoplastic Left Heart Syndrome

**Schematic drawing 1:** Comparison of a normal heart anatomy versus Hypoplastic Left Heart Syndrome

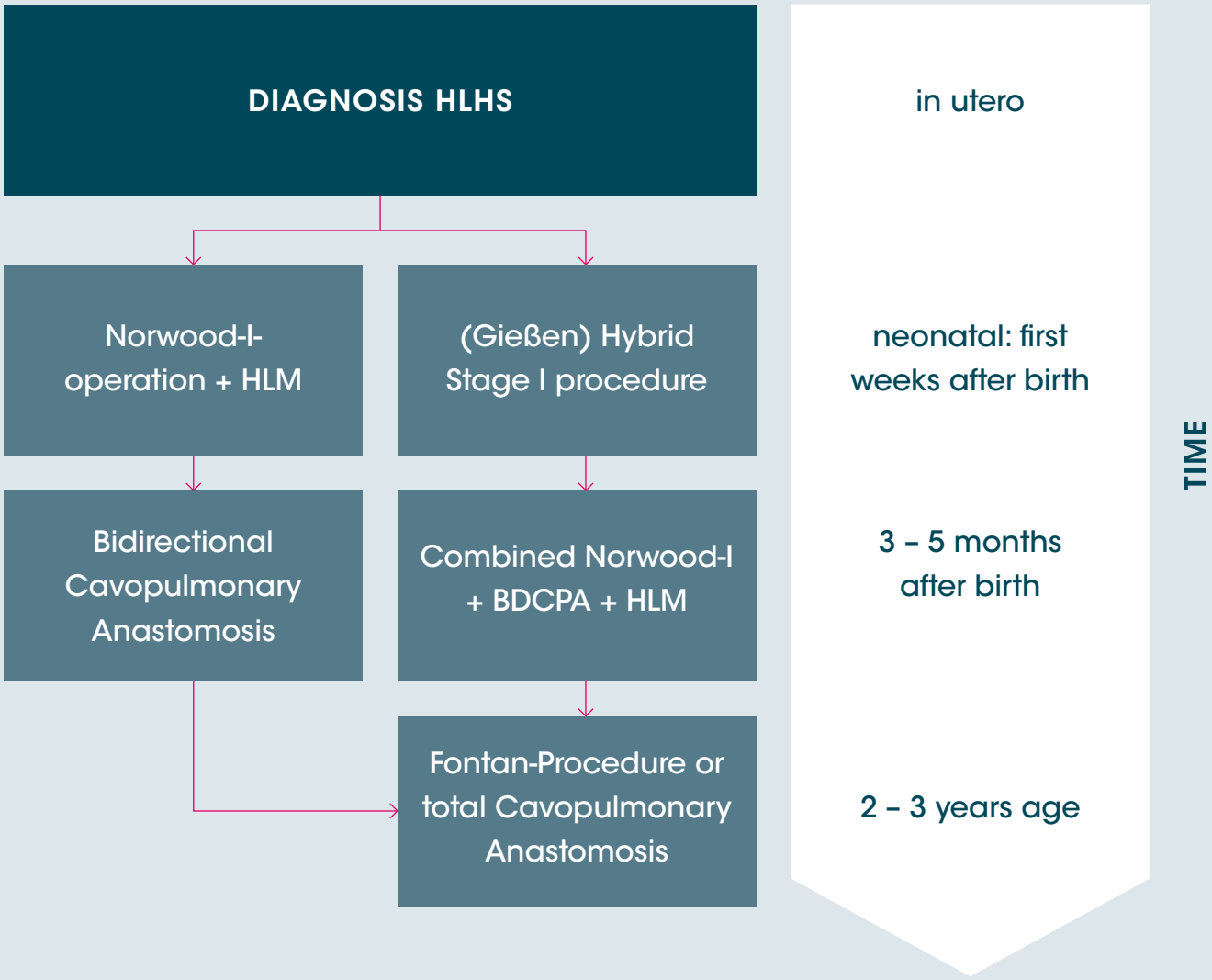
Hypoplastic Left Heart Syndrome (HLHS) is the term used for a variety of simultaneously occurring malformations of the heart and aorta in neonates, that are classified within the category LVOTO (Left ventricular outflow tract obstruction) together with the CHD subtypes coarctation of the aorta and aortic stenosis[3].

HLHS has a prevelance of 0.178 per 1000 birth and represents 2.56% of all CHD subtypes.[4]

HLHS is characterized by an underdeveloped left ventricle that is completely closed off from the aorta, so that blood flow to the aorta is provided by the ductus arteriosus to ensure that essential organs are supplied with blood (see schematic drawing 1).

HLHS is among the most serious congenital heart defects and is fatal in 99% of cases if left untreated.

# THERE ARE TWO DISTINCT APPROACHES TO TREAT HLHS:




Sources: 1 M, Skovránek J (1989) Prevalence, treatment, and outcome of heart disease in live-born children: a prospective analysis of 91,823 live-born children. Pediatr Cardiol 10:205–211)

2 (Benjamin EJ, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. Circulation. 2017 Mar 7;135(10):e146-e603. doi: 10.1161/CIR.0000000000000485. Epub 2017 Jan 25. Erratum in: Circulation. 2017 Mar 7;135(10 ):e646. Erratum in: Circulation. 2017 Sep 5;136(10 ):e196. PMID: 28122885; PMCID: PMC5408160.)

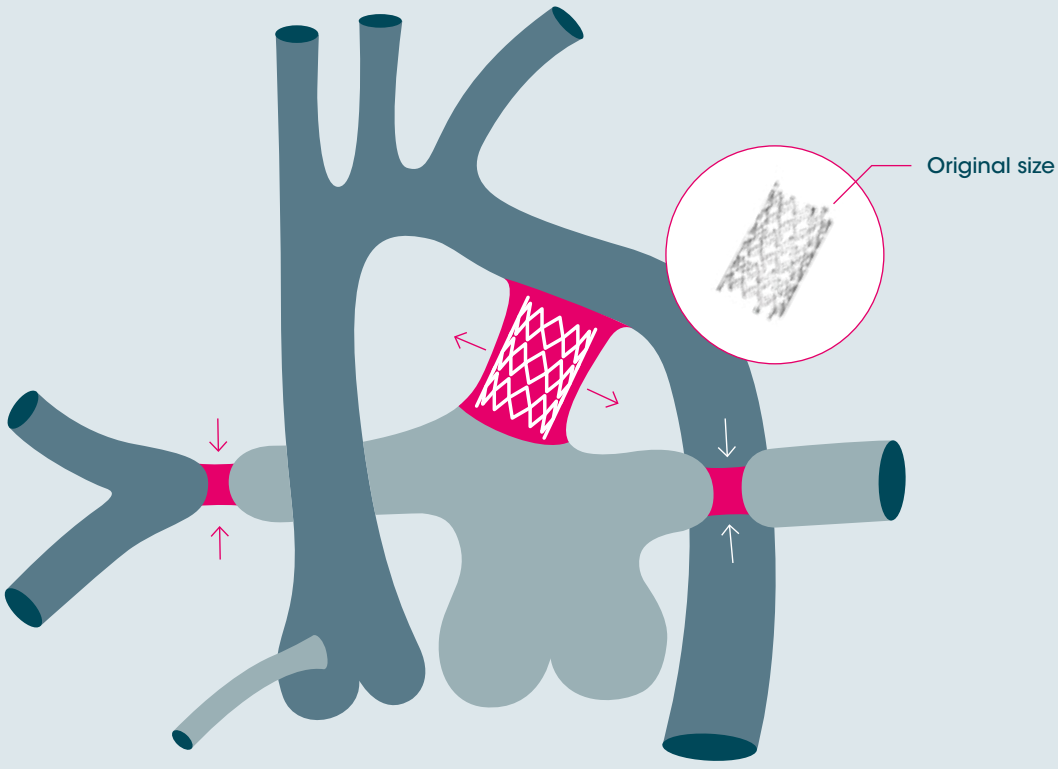
3 Classification of CHD subtypes based on Bottos's method (2007).

4 (Yingjuan Liu, Sen Chen, Liesl Zühlke, Graeme C Black, Mun-kit Choy, Ningxiu Li, Bernard D Keavney, Global birth prevalence of congenital heart defects 1970–2017: updated systematic review and meta-analysis of 260 studies, International Journal of Epidemiology, Volume 48, Issue 2, April 2019, Pages 455–463, https://doi.org/10.1093/ije/dyz009)

# THE HYBRID PROCEDURE

The hybrid procedure is a cooperative procedure combining techniques of catheter intervention and cardiac surgery.

## sinus-SuperFlex-DS



After birth, both branches of the pulmonary artery are surgically narrowed by reducing the high flow of blood to the lungs and directing the blood through the patent ductus arteriosus into the aorta. A stent is implanted to maintain blood flow through the ductus arteriosus.

The open-cell design of the sinus-SuperFlex-DS stent is designed to provide the flexibility and radial force required to maintain patency of the ductus arterios until its surgical removal.

# ADVANTAGES OF THE HYBRID INTERVENTION FOR THE NEONATAL / INFANT PATIENT – AT A GLANCE

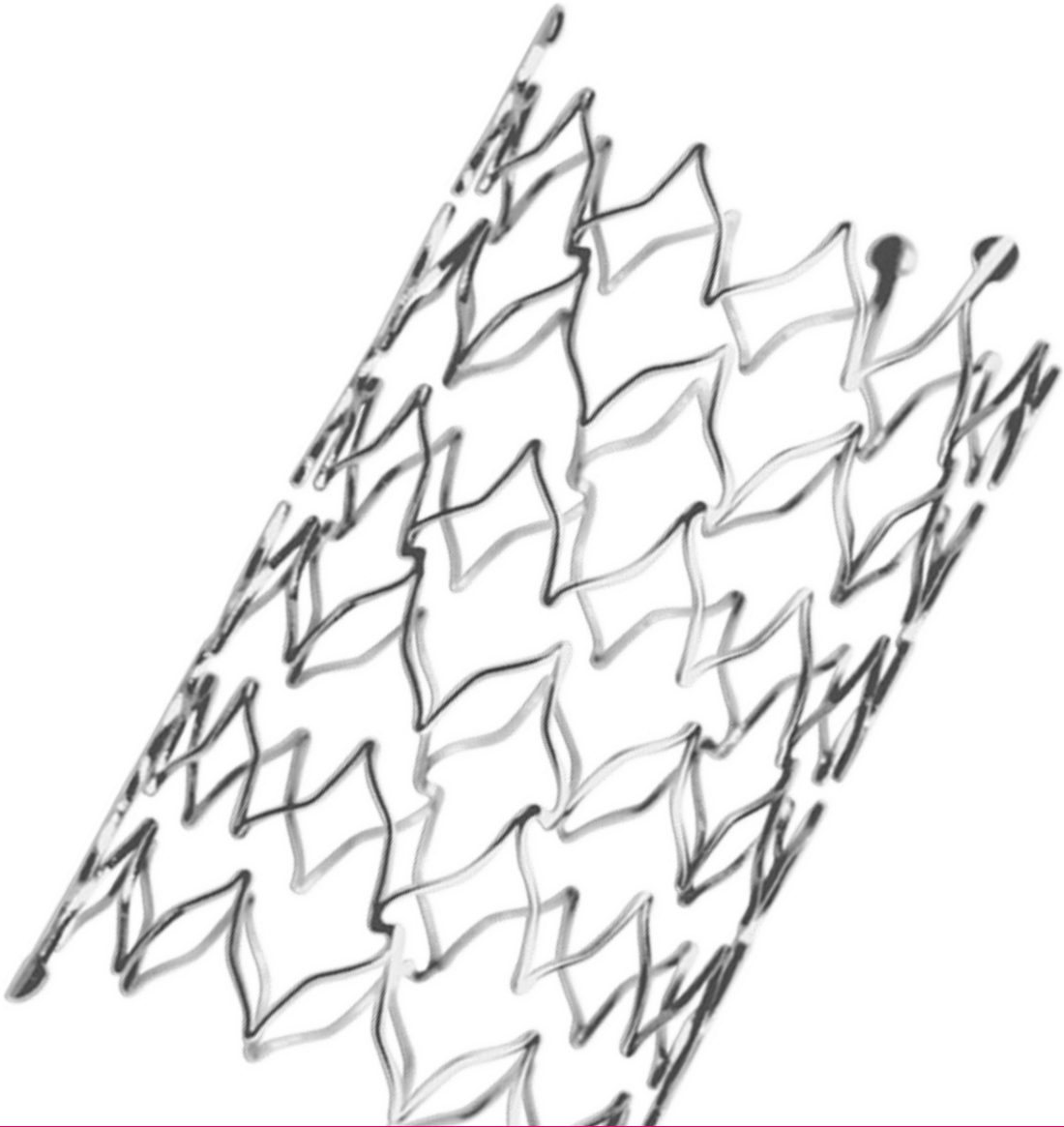
**The Hybrid Intervention avoids a surgical intervention involving a Heart-Lung-Machine (HLM) very early after birth:**
The complex reconstruction of the aorta does not take place immediately after birth but only at an age of 4–6 months – when the child is more stable.

**The Hybrid approach is overall regarded as less invasive to the neonatal / infant patient:**
There is NO complete circulatory or cardiac arrest required thus reducing the risk for neurological damage and cardiac muscle damage.

Source: 1 Mienert, Tine: Das hypoplastische linke Herz: Gießen-Hybrid-Prozedur Stage I mit Einsatz eines speziell entwickelten, selbstexpandierenden Ductus-Stents

# EXCEPTIONAL SOLUTIONS FOR EXCEPTIONAL SITUATIONS.

The self-expanding sinus-SuperFlex-DS vascular stent system is specifically designed to provide temporary patency of the ductus arteriosus. It is indicated to improve or maintain duct dependent systemic circulation in neonates and infants with hypoplastic left heart syndrome/complex (HLHS/HLHC).



# UNIQUE DESIGN FEATURES

## sinus-SuperFlex-DS

- The **first and only dedicated Ductus Arteriosus stent** on the market
- Available in an **extensive product range** which allows in the vast majority of patient morphologies for the entire duct to be covered with one single stent
- Open-cell system for a **very high level of flexibility** and an optimal vessel adaptation
- Tantalum markers designed for a good radiopacity and **precise stent placement**
- Electro-polishing process for particular smooth surfaces and **reduced thrombogenicity**

The **sinus-SuperFlex-DS** stent has been specifically designed for the treatment of **Hypoplastic Left Heart Syndrome** and has **Class III approval** (93/42/EEC). The stent design is based on the proven sinus technology, in which the stents are **manufactured seamlessly** from one piece of nitinol, completely without junctions or soldered joints. This approach makes them particularly **resistant to stent breakage** and gives them a **very high radial force even with the shortest stent lengths**. A electropolishing process ensures particularly smooth surfaces and additionally **reduces thrombogenicity**[1].

# OPTIMAL PATIENT SAFETY

A 4F covered delivery system ensures a simple and gentle access route via the femoral artery. Thus no need for a long vascular sheath or a vascular sheath traumatising of the cardiac structure[2]

Lower risk of stent embolization due to the open-cell stent design[2]

Stent release is possible without balloon dilatation

No risk of complete interruption of the blood flow in the duct which is often fatal[2]

No risk of embolisation caused by retraction of poorly deflated balloons when using balloon expandable stents[2]

Sources: 1 https://pubmed.ncbi.nlm.nih.gov/16095686/
2 Mienert, Tine: Das hypoplastische linke Herz: Gießen-Hybrid-Prozedur Stage I mit Einsatz eines speziell entwickelten, selbstexpandierenden Ductus-Stents

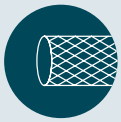
Arterial

maximum .018 inch guide wire

4F Ø delivery system

Nitinol stent

Braided sheath



Radiopaque markers

Anti-Jump Technique™

Open-cell design

# MAXIMUM FLEXIBILITY

The highly flexible 4F application system of the sinus-DS stents provides two access options:

**TRANSVENOUS:**
over the femoral vein

**TRANSARTERIAL:**
over the femoral artery

Pull-back system

## DETAILS sinus-SuperFlex-DS

### LENGTHS

12 mm | 15 mm | 18 mm

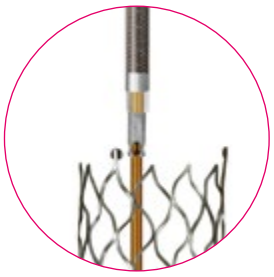
20 mm | 22 mm | 24 mm

### DIAMETERS

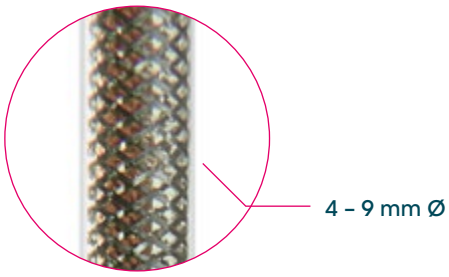
4 mm | 5 mm | 6 mm | 7 mm | 8 mm | 9 mm

The application system features an exceptionally easy-to-use pull-back-system. Radiopaque markers, braided sheath and atraumatic soft tip facilitate guidance and positioning. To ensure accurate positioning, the stent is fixed in the application device by the anti-jump system – an integrated mechanism which prevents the stent from jumping.

Atraumatic soft tip



Anti-Jump Technique™




Braided outer sheath

## ORDER CODES

| | Lengths | | | | | |
|---|---|---|---|---|---|---|
| | 12 | 15 | 18 | 20 | 22 | 24 |
| Ø4 | 8804-2012* | 8804-2015 | 8804-2018 | 8804-2020 | 8804-2022* | 8804-2024 |
| Ø5 | 8805-2012* | 8805-2015 | 8805-2018* | 8805-2020 | 8805-2022* | 8805-2024 |
| Ø6 | 8806-2012* | 8806-2015 | 8806-2018* | 8806-2020 | 8806-2022* | 8806-2024 |
| Ø7 | 8807-2012 | 8807-2015 | 8807-2018 | 8807-2020 | 8807-2022 | 8807-2024 |
| Ø8 | 8808-2012 | 8808-2015 | 8808-2018 | 8808-2020 | 8808-2022 | 8808-2024 |
| Ø9 | – | 8809-2015 | – | 8809-2020 | 8809-2022 | 8809-2024 |

* non-stock item

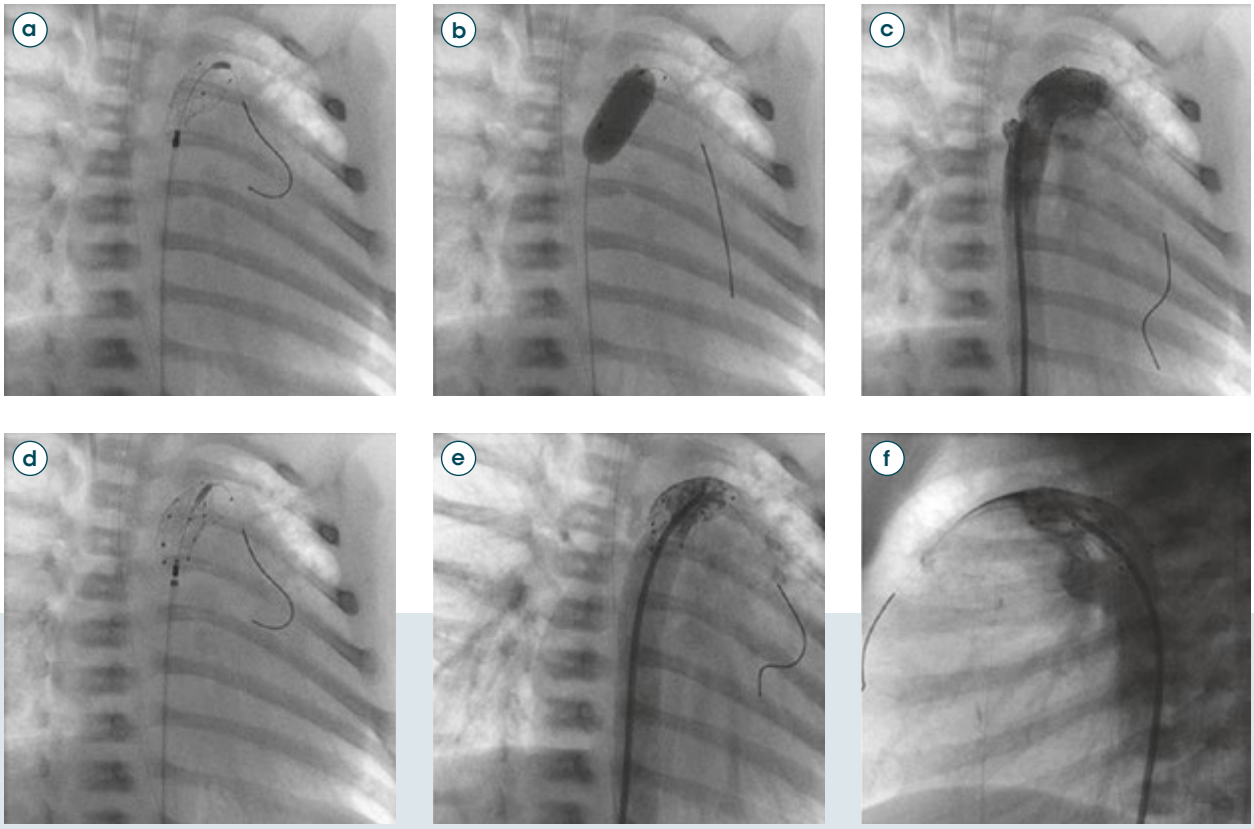
4F / 85 cm delivery system

Adapted to 0.018 inch guide wire

Tantal marker distal 4 / proximal 4

Box / 1 unit

# DUCTAL STENTING PROCEDURE




(a) The sinus-SuperFlex-DS stent (8x18mm) shows incomplete expansion at its pulmonary end after placement into the Ductus Arteriosus.

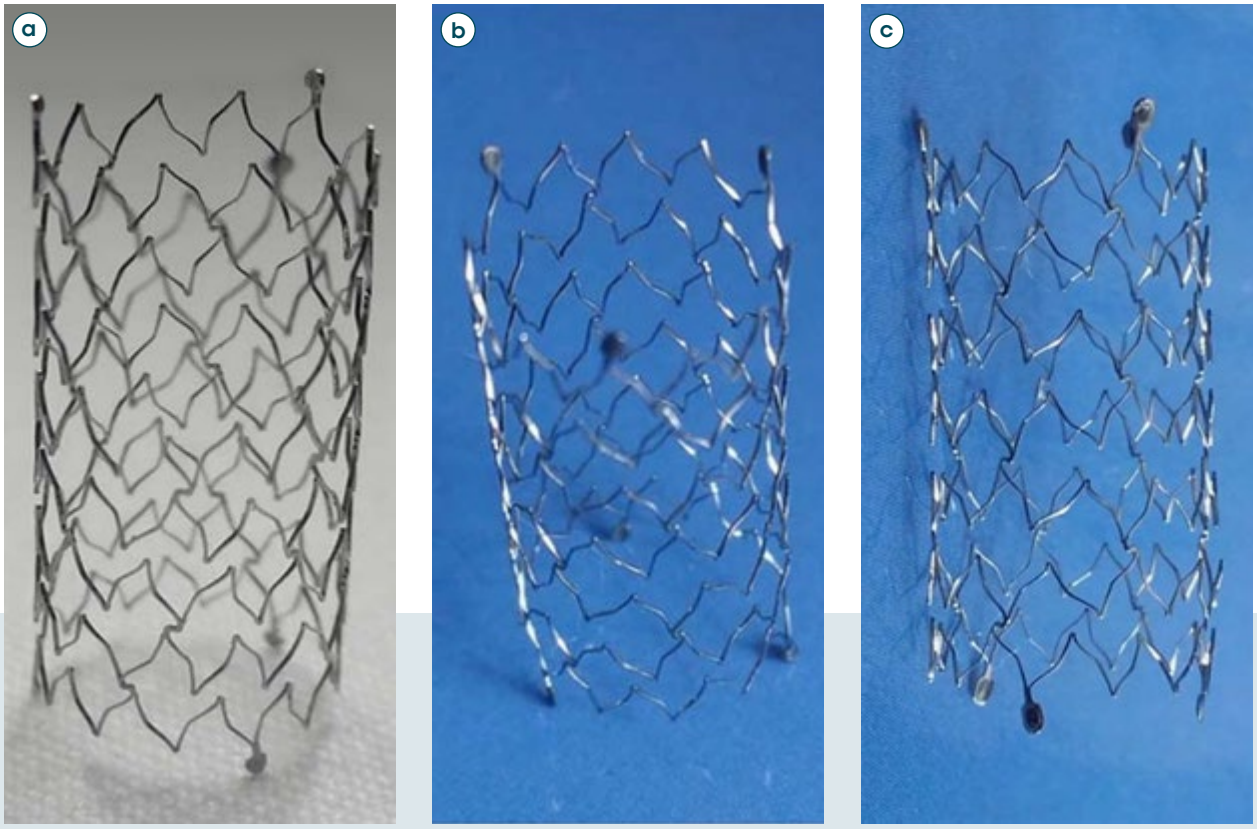
(b) Subsequent dilation of the stent using a pediatric valvuloplasty catheter (8 x 20mm) results in complete expansion of the stent.

(c) Angiographic assessment reveals inadequate coverage of the Ductus Arteriosus.

(d) Placement of a second sinus-SuperFlex-DS stent (8 x 15mm) implanted in an overlapping technique.

(e) (f) Favorable angiographic result complete stent expansion and total coverage of the Ductus Arteriosus with sufficient safety margins

# The sinus-SuperFlex-DS stent before implantation and seven weeks after implant removal – the stent was easily removed from the patient not requiring any dissection and leaving smooth tissue behind.




(a) An example of a self-expanding, open-cell, nitinol sinus-SuperFlex-DS stent.

(b) and (c) 7 weeks after hybrid ductal stenting, the stent was easily slid out not requiring any dissection and leaving smooth tissue behind.

Sources:
Left page: Butera, Gianfranco & Chessa, Massimo & Eicken, Andreas & Thomson, John. (2019). Atlas of Cardiac Catheterization for Congenital Heart Disease. 10.1007/978-3-319-72443-0.
Chapter 29. Dietmar Schranz and Hakan Akintuerk: Hypoplastic Left Heart Syndrome: The Giessen Hybrid Approach. Page 255 - 261.
This page: Goreczny, Sebastian & Qureshi, Shakeel & Rosenthal, Eric & Krasemann, Thomas & Nassar, Mohamed & Anderson, David & Morgan, Gareth. (2016). Comparison of self-expandable and balloon-expanding stents for hybrid ductal stenting in hypoplastic left heart complex. Cardiology in the Young. 27. 1-9. 10.1017/S1047951116001347.

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