At the end of this users will able to.

- Identify a STENTYS Case
- Understand how self apposing stent behave differently to BES and what that means for the procedure
- Know how to deploy a Xposition S
  - Lesion preparation
  - Device Selection and preparation
  - Device deployment
  - Catheter Withdrawal
  - Post Dilation
- Disconnect the stent for a Bifurcation
- Understand the causes of retraction force and how to minimise retraction force
Dedicated to challenging lesions
UNDERSTANDING THE BIOMECHANICS OF SELF-APPOSING STENT
Self-Expanding Stents have a high expansion force to dilate the lesion allowing direct stenting, this force decreases as the stents diameter increases but a fully expanded stent continues to exert a moderate continual force on the vessel wall.

Self-Apposing Stents have a much lower expansion force to completely and continuously appose to the vessel wall and like Balloon expandable stents require balloon dilation to fully dilate the lesion.

Balloon-Expandable Stents have no expansion force relying completely on a balloon to dilate the lesion and to expand the stent.

Self-Apposing Stents have
- A low expansion force to minimise vessel overexpansion and continual Barotrauma.
- A much higher Radial Force to resist compression of the stent
- No inherent tendency to recoil

Unlike Balloon expandable stents, Self-Apposing stents are able to recover from being crushed as any decrease in stent diameter increases the COF allowing the stent to recover

However like Balloon expandable stent, Self-Apposing stents rely on a balloon for lesion dilation

Therefore lesion preparation with Self-Apposing stent is critical to the success of the procedure
The mechanical differences between Self-Expanding and Self-Apposing® Nitinol Stents (Self-Apposing doesn’t mean Lesion Expanding)

As the Stent is deployed and the stent diameter increases the expansion force of the stent decreases.
Oversizing a self-apposing stent may exert excessive force of the vessel wall, and may issues on the withdrawal of the delivery system.
Therefore care should be taken to avoid over sizing the stent.

Due to the nature of Nitinol it is worth noting that unlike a balloon expandable stent it is not possible to overexpand or deform a Self-Apposing stent

To avoid excessive force on the vessel wall and possible retraction issues care should be taken to avoid over sizing the stent.
Self-Apposing® Stents are sensitive to lesion under-expansion and therefore require complete lesion expansion, through lesion preparation and post dilation.

Testing demonstrates that lesion under-expansion dominates the risk of Stent Thrombosis (under expansion >25% increases the risk more than 10 fold) – Post dilation reduces this risk independent of stent type.

### Controlled Underexpansion

<table>
<thead>
<tr>
<th>#1 vs #2</th>
<th>Favors #1</th>
<th>Favors #2</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Stents (STENTYS vs. BEx)</td>
<td><img src="#" alt="Graph" /></td>
<td><img src="#" alt="Graph" /></td>
<td>1.37 (0.81 - 2.34)</td>
</tr>
<tr>
<td>All Stents (&lt;25% vs. &gt;=25%)</td>
<td><img src="#" alt="Graph" /></td>
<td><img src="#" alt="Graph" /></td>
<td>0.083 (0.021 - 0.33)</td>
</tr>
<tr>
<td>STENTYS (&lt;25% vs. &gt;=25%)</td>
<td><img src="#" alt="Graph" /></td>
<td><img src="#" alt="Graph" /></td>
<td>0.03 (0.0021 - 0.52)</td>
</tr>
<tr>
<td>BEx (&lt;25% vs. &gt;=25%)</td>
<td><img src="#" alt="Graph" /></td>
<td><img src="#" alt="Graph" /></td>
<td>0.21 (0.053 - 0.86)</td>
</tr>
</tbody>
</table>

Testing performed at ????? - final report pending
CASE SELECTION FOR A SELF-APPOSING STENT
Xposition S is designed for challenging lesions that have a variance in vessel diameter of $\geq 1\text{mm}$, include a vessel diameter of $\geq 4.5\text{mm}$ and/or include a TIMI TG $\geq 4$. 
By actively adapting and self-apposing to variances in vessel diameter

<table>
<thead>
<tr>
<th></th>
<th>Nominal Pressure</th>
<th>Overexpansion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synergy</td>
<td><img src="image1" alt="Synergy Nominal Pressure" /></td>
<td><img src="image2" alt="Synergy Overexpansion" /></td>
</tr>
<tr>
<td>Xience Xpedition</td>
<td><img src="image3" alt="Xience Xpedition Nominal Pressure" /></td>
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<td>Orsire</td>
<td><img src="image5" alt="Orsire Nominal Pressure" /></td>
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<tr>
<td>Ultimaster</td>
<td><img src="image7" alt="Ultimaster Nominal Pressure" /></td>
<td><img src="image8" alt="Ultimaster Overexpansion" /></td>
</tr>
<tr>
<td>Resolute Onyx</td>
<td><img src="image9" alt="Resolute Onyx Nominal Pressure" /></td>
<td><img src="image10" alt="Resolute Onyx Overexpansion" /></td>
</tr>
<tr>
<td>Biomatrix A. Chroma</td>
<td><img src="image11" alt="Biomatrix A. Chroma Nominal Pressure" /></td>
<td><img src="image12" alt="Biomatrix A. Chroma Overexpansion" /></td>
</tr>
</tbody>
</table>

Xposition S is able to remove both the complications of distal oversizing and proximal undersizing.

**Too small**
- Proximal Malapposition, Underexpansion
  - Stent thrombosis
  - Restenosis

**Too large**
- Distal Overdilation
  - Dissection/Perforation
  - No reflow
  - Plaque Shift
and those procedural risks inherent in trying to optimise a conventional DES to varying diameters or thrombus presence.

Self-Apposing® Stents demonstrate complete and continuous apposition despite changes in vessel diameter

In STEMI Patients there was a +19% Increase in Mean Distal Reference Vessel Area at 3 days

Pooled data from STENTYS APPOSITION II and APPOSITION IV STEMI Trials
Values between measured data points are based on linear extrapolation and are not necessarily indicative

J Am Coll Cardiol Intv. 2012;5(12):1209-1219
Eurolntervention 2016;11:e1267-e1274

Why use a Self-Apposing stent on vessels with a variance in vessel diameter of ≥1mm

A Self-Apposing stent will actively adapt to the variance in vessel diameters without the need for stent optimisation. Pre and post dilation may be required but only to ensure complete lesion expansion. Thus reducing the potential complications of vessel over dilation, of leaving a malapposed stent and of distal dissection.
Why use a Self-Apposing stent in vessels with a heavy thrombus load?

A Self-Apposing stent will actively adapt to the increased lumen diameter caused by thrombus absorption over time.

Heavy thrombus and spasm may also obscure the true vessel dimensions, the sizing flexibility of a Self-Apposing stent means they will adapt to the true vessel dimensions as the thrombus dissolves.
Why use a Self-Apposing stent in vessels with a diameter greater than 4.5mm?

A Self-Apposing stents are designed adapt to large diameters without losing their cell structure, maintaining their scaffolding effect and drug elution into the vessel wall.
Excessive tortuosity may make it more difficult to reach the lesion but will apply additional friction into the system and will increase the force required to withdraw the system after stent deployment, and increase the risk of guide catheter advancement and subsequent catheter induced dissection.
However due to the nature of the device and deployment of a Self-Apposing stent it is advised to avoid lesions that involve heavily tortuous access and or extreme calcification

Extreme calcification, calcification that fails to respond to lesion preparation and maintains a residual stenosis of greater that 30% and a lumen diameter of less than 2mm, will greatly increase the retraction force and the risk of leaving an under expanded stent – a risk factor for Stent Thrombosis
SELF-APPOSING STENT PROCEDURE
Balloon Delivery System - Overview

6F Guiding Catheter compatible
Distal Crossing Profile
- 0.056" (1.42 mm) for Large system
- 0.051" (1.3 mm) for Medium / Small systems

<table>
<thead>
<tr>
<th>Compliance Chart</th>
<th>PRESSURE</th>
<th>2.5-3.0mm (Small)</th>
<th>3.0-3.5mm (Medium)</th>
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</tr>
<tr>
<td>12atm (1216kPa)</td>
<td>REC*</td>
<td>2.70mm</td>
<td>3.15mm</td>
<td>3.65mm</td>
</tr>
<tr>
<td>14atm (1419kPa)</td>
<td>RBP</td>
<td>2.80mm</td>
<td>3.26mm</td>
<td>3.74mm</td>
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* REC Maximum deployment pressure (Recommended Implantation Pressure)
Balloon Delivery System – Understanding the Markers

Prior to Deployment

After Deployment, note slight withdrawal of the delivery system

Balloon Markers indicate the distal and proximal ends of the stent on the delivery system

Distal and proximal Stent Markers overlap the balloon markers but become more visible after deployment
A Self-Apposing stent is designed to appose to the vessel not dilate a lesion therefore lesion preparation is critical

- The lesion should be prepared in such a way that it’s diameter is at least 2.0mm and the residual stenosis in less than 30%.
  - This is in particular applicable for tight and heavily calcified lesions in these cases the use of pre-dilation balloon sized to the reference vessel diameter is recommended.
  - In the event of inadequate lesion preparation consider the use of Rotoblation and or Cutting / Scoring balloon to achieve <30% residual stenosis and a >2mm diameter
  - If adequate lesion preparation is not possible do not continue with the deployment of a Self-Apposing stent.
- If necessary, excessive thrombus should be removed following standard thrombus removal techniques.

Note: When ready to proceed with the STENTYS-Stent deployment, if deemed appropriate by the physician, an anticoagulation treatment (e.g. heparin) should be given intravenously or intra-arterially to the patient, per institutional standards of practice.
Selecting to **correct stent size**, reduces the retraction force and minimises the risk of vessel overexpansion.

Stent diameter should be selected according to the diameter of the distal reference vessel:
- At the stent size boundaries (3.0 & 3.5mm diameter), use the smaller size.
- Ensure that the maximum vessel diameter falls into the indicated size range.
- Care should be taken to avoid oversizing the stent.
Prior to introducing the device, ensure that the Guiding Catheter is stable and able to provide sufficient support.

Remove the clear Teflon cover over the distal end of the STENTYS STENT SYSTEM.

- Inspect visually the distal end of the STENTYS STENT SYSTEM to ensure that the STENTYS-Stent is contained within the splitable sheath. Do not use if the STENTYS-Stent is partially deployed.
- Ensure that the wire shipping mandrel was removed with the Teflon cover

**Note:** DO NOT apply negative or positive pressure to the balloon prior to reaching the lesion site.

Insert the proximal end of the guidewire already present in the patient into the tip of the STENTYS STENT SYSTEM.
Utilizing the distal and proximal markers of the STENTYS Delivery System, place the stent in desired position

Attached the inflation device (only partially filled with contrast media 1:1 diluted with normal saline) to the inflation port.

Purge the system of air using negative pressure

Slowly inflate the balloon to Recommended deployment pressure (12atm).

The STENTYS-Stent deployment is completed when the balloon of STENTYS Delivery System is fully inflated pass the proximal marker of the delivery system by 4mm.

If the waist of the balloon fails to resolve at 12atm, inflate the balloon to 14atm.

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* REC Recommended deployment pressure
Deflate the balloon by pulling negative on the inflation device for at least 30 seconds. Ensure that the balloon is fully deflated before attempting to move the STENTYS Delivery System.

Prior to removal of the STENTYS Delivery System, withdraw the tip of the Guiding Catheter so that it is 2 cm from the proximal stent marker.

Remove the STENTYS Delivery System, keeping in place the 2cm distance between the Guiding Catheter and the proximal stent marker.

Note: During STENTYS Delivery System removal:

- Some resistance will be felt initially during removal. This is inherent to the procedure. Attention should be brought to the possible forward movement of the Guiding Catheter.

Ensure that the entire STENTYS Delivery System has been completely removed from the guidewire prior to retightening the hemostatic valve.

The STENTYS Delivery System cannot be used, at any time, as a dilation device.
Avoiding Guiding Catheter and Stent interaction reduces the retraction force

Retraction force with and without Guiding Catheter impingement on the sheath
Managing High Retraction forces

• The retraction force is a static load, to withdraw the system apply a steadily increasing pull force to the system until the system starts to move.
  • Short sharp pulls on the system, may cause the Guiding Catheter to advance and interact with the stent and should be avoided.

• Tension should be kept on the Guiding Catheter to help reduce any retraction force and prevent any forward movement of the Guiding Catheter.
  • Friction inside the Guiding Catheter acts a force multiplier (upto 5X the force put on the distal sheath).

• In the majority of cases a high retraction force is related to either
  • An under prepared lesion, taking care to fully prepare the lesion helps to avoid high retraction forces.
  • An oversized stent, care should be taken to select the correct stent size.
  • A highly calcified lesion, such lesions should be avoided, at least for the first few Xposition S cases
Post-dilation is **strongly recommended** using a non-compliant balloon of same size as RVD.

- Applied pressure should be at nominal value or higher if needed.
- No part of the STENTYS-Stent should be left under-expanded with respect to the reference vessel diameter.

The STENTYS Delivery System must not be reinserted in any vessel and cannot be used, at any time, as a dilation device.

- The splitable sheath remains permanently attached to the balloon catheter, it is not possible to remove this sheath.
Selecting and Preparing the Stent

Use the distal vessel diameter to determine the STENTYS-stent diameter. At the stent diameter range boundaries, it is recommended to use the smaller size. For example, a vessel diameter of 3.5mm Reference Vessel Diameter (RVD) would receive a 3.0-3.5mm STENTYS-stent, not a 3.5-4.5mm one.

Do not apply negative or positive pressure to the balloon prior to reaching the lesion site.

Post dilation

In order to ensure optimal stent expansion, post dilation of the STENTYS-stent with a non-compliant balloon is strongly recommended with a balloon diameter according to the RVD. Applied pressure should be at nominal value, or higher if needed. No part of the STENTYS-stent may be left under-expanded with respect to the RVD.

Key Procedural Points

Lesion Preparation

The target lesion should be prepared in such a way that its minimum lumen diameter is at least 2.0mm, and residual stenosis should be less than 30% prior to using the STENTYS-stent. This is particularly important for tight and heavily calcified lesions to minimise withdrawal force.

Stent Deployment

It is recommended to slowly inflate the balloon to at least the recommended deployment pressure (REC) (12atm). Ensure visually that the balloon is fully inflated and increase pressure to Rated Burst Pressure (RBP) (14atm) if necessary.

Withdrawal

To facilitate un-jailing of the sheath, it is recommended to withdraw the Guiding Catheter and constantly adjust its position to maintain a 2cm gap between the Guiding Catheter distal tip and the proximal marker of the STENTYS-stent.
BIFURCATIONS
Disconnectable Bridges

- The combination of flexion & rotation by a balloon allows the stent interconnector technology to disconnect. The stent can only disconnect in the cell where the balloon is passed.
- Disconnection does not affect the radial force of the stent.
- Post-dilation of the stent does not cause disconnections as it does not create any strain/stress on the interconnectors.

Once disconnected, connector remains aligned with surface of the stent, therefore no impact on vessel injury or balloon puncture.

Opening possible at any level along stent body (except the 2 most distal and proximal rows of stent.)
Disconnection feature allows for side branch access if required, facilitating a balloon expandable type of provisional bifurcation stenting.

<table>
<thead>
<tr>
<th>Size*</th>
<th>Recommended vessel diameter</th>
<th>Minimum Side-branch diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small</td>
<td>~2.5 to 3.0mm</td>
<td>≥2.20</td>
</tr>
<tr>
<td>Medium</td>
<td>~3.0 to 3.5mm</td>
<td>≥2.25</td>
</tr>
<tr>
<td>Large</td>
<td>~3.5 to 4.5mm</td>
<td>≥2.50</td>
</tr>
</tbody>
</table>

The stent should only be disconnected if the bifurcation angle is between 30° and 70°.
Opening the stent for Side Branch Access, cross the cell closest to the carina

Position the guidewire into the side branch taking care to cross into the most distal cell, the cell closest to the carina

Inflate a regular balloon, sized to the side branch diameter to at least at 8 atm at the sidebranch opening to disconnect the bridges.

Deflate and withdraw the balloon allowing the stent to expand fully to create the opening to the side branch. Kissing is not mandatory. However confirm that the stent is fully expanded and post dilate if required

The combination of flexion & rotation allows the stent interconnector technology to disconnect. The stent will only disconnect in the cell where the balloon is passed

Disconnection does not affect the radial force of the stent

Post-dilation of the stent does not cause disconnections as it does not create any strain/stress on the interconnectors
CONCLUSION
**Summary Overview**

**Case Selection**
Avoid heavy calcification and tortuous anatomy

**Lesion Preparation**
<30% residual stenosis
>2mm lumen diameter

**Stent Size Selection**
Size to Distal RVD
Do not Oversize

**Stent Delivery**
Inflate to ≥12atm*

**System Withdrawal**
Maintain Guiding Catheter
2cm from proximal stent marker

**Post Dilation**
Dilate to RVD

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*RBP is 14 atm*
As there is a learning curve to mastering a Self-Apposing stent, it is recommended to start with simple elective cases for the first 5 cases.

Initial Ideal Case Check list
- Vessel has diameter variance or has a heavy Thrombus load or includes large vessel segment
- Relatively non tortuous access
- Good guide catheter support with a stable position
- No severe calcium presence either at the lesion or in the access
- Lesion can be completely prepared
- If a bifurcation is involved it should be relatively easy to manipulate a guide wire into the side branch

Left Main and Ostial lesions should not be attempted as initial cases.