The coating is applied primarily on the abluminal surface.

1. 4-year clinical outcomes of dedicated bifurcation Axxess™ stent in DIVERGE trial, document 11059-000 at Biosensors Intl
5. Data on file at Biosensors Intl
6. Left main stent is not CE approved

Axxess™ Drug Eluting Coronary Bifurcation Stent System is CE approved.  

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<tr>
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<td>AXBF-3511</td>
<td>AXBF-3514</td>
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Pilot study using bare metal stent Axxess™ platform  
In-segment restenosis at 6 months

FRANCE, GERMANY

Pilot study using bare metal stent Axxess™ platform  
In-segment restenosis at 6 months

Axxess-matched side to compare Axxess BMS along with Biolimus™ with Culotte technique using Palmaz®

BIOSENSORS EUROPE SA  
Rue de Lausanne 29  
1110 Morges  
Switzerland  
Tel: +41 (0)21 804 80 00  
Fax: +4 1 (0)21 804 80 01

BIOSENSORS INTERVENTIONAL TECHNOLOGIES PTE LTD  
Blk 10 Kaki Bukit Avenue 1  
#06-01/04  
Singapore 417 942  
Tel: +65 621 3 5725  
Fax: +65 621 3 5737

AXXENTlobe  
Left Main DES

COBRA  
Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Culotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE, GERMANY

Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Culotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE

Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Culotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE, BRAZIL, NEW ZEALAND

EUROPE

Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Culotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE

Randomized multicenter trial to compare the Axxess™ DES to the Cullotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE, AUSTRALIA, NEW ZEALAND

AXXESS PLUS n= 139  
5-year follow up available  
Study completed

AXXENT n= 33  
Left main bifurcation  
Stent strut coverage assessed by OCT at 6 months

COBRA  
Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Culotte technique using Xience V®

Stent strut coverage assessed by OCT at 9 months

EUROPE

DIVERGE n= 302  
4-year follow up available  
Study completed

6-month follow up completed

www.biosensors.com
Tailored bifurcation therapy

Dedicated self-expanding platform that conforms to the specific bifurcation anatomy

- Full bifurcation lesion coverage without creating a false carina

Safety and efficacy confirmed out to 4 years

- 3.3% Primary endpoint (death, MI and/or UI)
- 4.8% 18% 9% 1.4%

Definite stent thrombosis at 4 years

- 1.3% 1.3% 5.2% 2.6% 2.5%

Proven safety of a dedicated bifurcation DES with an abluminal biodegradable polymer

- Very low restenosis rate in bifurcation lesions

Restenosis in DIVERGE at 9 months

- Any in-segment bifurcation restenosis: 6.4%

Low in-stent late loss

- In DIVERGE at 9 months: 0.18 mm

Proven efficacy of the Biolimus A9™ drug

- Very low in-stent late loss (Axxess™ only)

Biolimus A9™ drug 10 times more lipophilic than Sirolimus

- Highest lipophilicity of the common limus drugs

- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

Abluminal biodegradable coating

- No drug carrier or drug inside the stent:
  - Early BAS-like endothelial coverage
  - Targeted drug release
  - Reduced systemic exposure

Definite stent thrombosis at 4 years

- 1.0% 1.3% 2.1% 2.0% 2.0%

Dedicated self-expanding platform

- Self-expanding nitinol stent that conforms to the specific bifurcation anatomy
- Excellent wall apposition
- Spans both vessels at the same time
- No false carina
- Does not cover the flow divider even in a full bifurcation reconstruction

Two models

- Reference vessel diameter: 3.0 ± 0.25 mm
- Max. proximal stent diameter: 3.75 mm
- Max. distal stent diameter: 6.00 mm

- Reference vessel diameter: 3.5 ± 0.25 mm
- Max. proximal stent diameter: 4.25 mm
- Max. distal stent diameter: 6.50 mm

References:
- 1
- 2
- 3
- 4
- 5
Dedicated self-expanding platform that conforms to the specific bifurcation anatomy

Tailored bifurcation therapy

Dedicated bifurcation stent
- Self-expanding nitinol stent that conforms to the specific bifurcation anatomy
  - Excellent wall apposition
  - Spans both vessels at the same time

No false carina
- Does not cover the flow divider even in a full bifurcation reconstruction

Bifurcation DES technology
Complete reconstruction possible

Proven safety of a dedicated bifurcation DES with an abluminal biodegradable polymer


definite stent thrombosis at 4 years

Safety and efficacy confirmed out to 4 years

Primary endpoints

\[
\text{MACE defined as death, MI and id-TLR}.
\]

Proven efficacy of the Biolimus A9™ drug

- Very low restenosis rate in bifurcation lesions

Low in-stent late loss (Axxess™ only) in DIVERGE at 9 months:

0.18 mm

Highest lipophilicity of the common limus drugs

- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

Axxess™ for the treatment of complex bifurcation lesions resulted in low 4-year event rates, with a MACE rate of 18.0%

Confined safety in DIVERGE
- The use of Axxess™ for the treatment of complex bifurcation lesions resulted in low 4-year event rates, with a MACE rate of 18.0%

Confirmed safety in DIVERGE
- Only one definite VLST attributed to Axxess; all events occurred in relation to Cypher
- VLST did not result in any death
- No VLST events between years 3 and 4

Very low definite VLST in DIVERGE trial results:
- Only one definite VLST attributed to Axxess; all events occurred in relation to Cypher
- VLST did not result in any death
- No VLST events between years 3 and 4

DIVERGE trial results
- Only one definite VLST attributed to Axxess; all events occurred in relation to Cypher
- VLST did not result in any death
- No VLST events between years 3 and 4

Full bifurcation lesion coverage without creating a false carina

Abluminal biodegradable coating
No drug carrier or drug inside the stent:
- Early BMS-like endothelial coverage
- Targeted drug release
- Reduced systemic exposure


defined stent thrombosis at 4 years

Definite stent thrombosis at 4 years

No drug carrier or drug inside the stent:
- Early BMS-like endothelial coverage
- Targeted drug release
- Reduced systemic exposure

BA9™ drug 10 times more lipophilic than Sirolimus

Highest lipophilicity of the common limus drugs
- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

BA9™ drug 10 times more lipophilic than Sirolimus

- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

For descriptive purposes only - Clinical trials with different protocols should not be compared.
Tailored bifurcation therapy

Dedicated self-expanding platform that conforms to the specific bifurcation anatomy

Full bifurcation lesion coverage without creating a false carina

Bifurcation DES technology Complete reconstruction possible

Proven safety of a dedicated bifurcation DES with an abluminal biodegradable polymer

Confirmed safety in DIVERGE
- The use of Axxess™ for the treatment of complex bifurcation lesions resulted in low 4-year event rates, with a MACE rate of 18.0%

Safety and efficacy confirmed out to 4 years

Proven efficacy of the Biolimus A9™ drug
- Very low restenosis rate in bifurcation lesions

Low in-stent late loss (Axxess™ only) in DIVERGE at 9 months^2: 0.18 mm

Any in-segment bifurcation restenosis: 6.4%

Definite stent thrombosis at 4 years^3

Axxess™ drug 10 times more lipophilic than Sirolimus^4

Highest lipophilicity of the common limus drugs
- Minimizes systemic exposure and reduces the drug circulating in the bloodstream
- Due to high lipophilicity, the drug is rapidly absorbed by tissue

Dedicated self-expanding platform

Self-expanding nitinol stent that conforms to the specific bifurcation anatomy
- Excellent wall apposition
- Spans both vessels at the same time

No false carina
- Does not cover the flow divider even in a full bifurcation reconstruction

Abdominal biodegradable coating

No drug carrier or drug inside the stent:
- Early BMS-like endothelial coverage
- Targeted drug release
- Reduced systemic exposure

BA9™ drug 10 times more lipophilic than Sirolimus

BA9™ 3 times more lipophilic than Zotarolimus

BA9™ 10 times more lipophilic than Everolimus

BA9™ 10 times more lipophilic than Sirolimus

Definite stent thrombosis at 4 years

Years

0
1
2
3
4

0
10
20
30
40
50
60
70
80
90
100

Primary endpoint
MACE at 9 months

\[ \text{Years} = 3 \]

\[ \text{Years} = 4 \]

Primary endpoint
MACE at 9 months

\[ 7.7\% \]

\[ 7.7\% \]

\[ 16.0\% \]

\[ 18.0\% \]

\[ 15.0\% \]

\[ 13.0\% \]

\[ 2.0\% \]

\[ 2.0\% \]

\[ 1.0\% \]

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**Pilot study for Axxess™ Left Main DES**

ifton et al., of a dedicated bifurcation Axxess™ stent (AXBF), presented at Biosensors Intl.

**DIVERGE Study: Australia, New Zealand**

n=302

To evaluate safety and performance of the Axxess™ DES for the treatment of the more challenging bifurcation lesions.

**AXXENT Study**

n=33

Pilot study for Axxess™ Left Main DES.

**COBRA Study**

n=40

Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Cullotte technique using Xience V.

In-segment restenosis at 6 months.

Pilot study using bare metal stent Axxess™ platform.

FRANCE, GERMANY

AXXENT PLUS n= 33

Parent vessel and side branch in-stent late loss at 6 months measured by QCA.

EUROPE

AXXESS PLUS n= 43

Pilot study using bare metal Axxess™ stent at 6 months.

EUROPE

AXXENT PLUS n= 139

Pilot follow-up available.

EUROPE

DIVERGE Study: Australia, New Zealand

n=302

MACE deaths, MI and TLR at 6 months.

EUROPE

DIVERGE n= 302

4-year follow-up available.

Europe, Australia, New Zealand

n=11924-000-EN – Rev.03

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www.biosensors.com
Clinical Program

AXXESS
FRANCE, GERMANY
Pilot study using bare metal Axxess™ platform
n= 43
6-month follow-up completed
Stent strut coverage assessed by OCT at 6 months.

AXXESS PLUS
DIVERGE NEW ZEALAND
Pilot study using bare metal Axxess™ platform
n=139
6-month follow-up available
Stent strut coverage assessed by OCT at 6 months.

DIVERGE
NEW ZEALAND
n=302
6-month follow-up available
Stent strut coverage assessed by OCT at 6 months.

AXXENT
EUROPE
Pilot study for Axxess™ Left Main DES™
n= 33
Late clinical follow-up available
Stent strut coverage assessed by OCT at 6 months.

COBRA
EUROPE
Randomized multicenter trial to compare Axxess DES along with BioMatrix™ with Cullot technique using Xience V™
n= 40
Enrolling
Stent strut coverage assessed by OCT at 6 months.

AXXESS PLUS
DIVERGE NEW ZEALAND

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