Vascular Intervention // Coronary Drug-Eluting Stent System

Orsiro®

Ultrathin struts. Outstanding patient outcomes.
Outstanding patient outcomes

Improving patient outcomes, year after year

BIOFLOW-V (n = 1,334) FDA pivotal trial\textsuperscript{1,2,3,4,5}

Significant differences in TLF observed at year 1 and 2 were maintained and further increased at year 3 (8.6% vs. 14.4%, \( p = 0.003 \)), driven by significant differences in TV-MI (5.5% vs. 10.1%, \( p = 0.004 \)) and ischemia-driven TLR (3.4% vs. 6.9%, \( p = 0.008 \)) that favor Orsiro over Xience.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{fig}
\caption{TLF and components at 12, 24 and 36 Months}
\end{figure}

\begin{table}
\centering
\begin{tabular}{lccc}
\hline
& Orsiro & Xience & \textsuperscript{\( p \)}-value\
\hline
\textbf{TV-MI rate} & 7.5 & 11.9 & 0.004\textsuperscript{\textdagger}
\textbf{TLF rate} & 14.4 & 14.4 & 0.003\textsuperscript{\textdagger}
\textbf{Ischemia-driven} & 3.4 & 6.9 & 0.008\textsuperscript{\textdagger}
\textbf{TLR rate} & 6.2 & 10.1 & 0.004\textsuperscript{\textdagger}
\end{tabular}
\caption{TLF and components at 12, 24 and 36 Months}
\end{table}

\begin{itemize}
\item \textbf{TLF} – Target Lesion Failure
\item \textbf{TV-MI} – Target Vessel Myocardial Infarction
\item \textbf{TLR} – Target Lesion Revascularization
\end{itemize}

\textsuperscript{\textdagger}As characterized with respect to strut thickness in the Bangalore et al. meta-analysis.\textsuperscript{11}

\textsuperscript{\textdagger\textdagger}Based on investigator’s interpretation of BIOFLOW-V primary endpoint results.

\textsuperscript{\textdagger\textdagger\textdagger}Compared to Xience in BIOFLOW-V, based on three consecutive years.

\textsuperscript{\textdagger\textdagger\textdagger\textdagger}p-values for 36-m frequentist analysis of BIOFLOW-V.

\textsuperscript{\textdagger\textdagger\textdagger\textdagger\textdagger}vs. Xience, based on 36-m frequentist analysis of BIOFLOW-V.

\textbf{Long-term performance}

In the randomized, all-comers BIOSCIENCE trial (n = 2,119)\textsuperscript{6}

Orsiro shows numerically equal or lower Stent Thrombosis (ST) in complex patients in comparison to Xience.

\begin{figure}
\centering
\includegraphics[width=\textwidth]{fig}
\caption{Definite ST at 5 years}
\end{figure}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{fig}
\caption{Definite or Probable ST at 5 years}
\end{figure}

\begin{itemize}
\item \textbf{Orsiro} \hspace{1cm} \textbf{Xience Prime} \hspace{1cm} \textbf{Abbott}
\end{itemize}
Ultrathin Struts – thinnest available in the US\(^7\)

**Thinner struts, faster endothelialization\(^6\)**

Improved outcomes start in the early phase

\[\text{48 hours} \quad \text{Thinner struts mean less vessel injury}\]

\[\text{Vascular Healing}\]

\[\begin{align*}
\text{30 days}^6 & \quad 88.4\% \\n\text{90 days}^6 & \quad 98.7\% 
\end{align*}\]

\[\text{\(\Delta\) 80.4% strut coverage}\]

\[\text{\(\Delta\) 98.7% strut coverage}\]

\[\text{\(\Delta\) 2.1} \quad \text{4.0} \quad (p = 0.008) \quad (p = 0.009)\]

\[\text{\(\Delta\) Driven by peri-procedural MI events (<48 hours). In-hospital rate may include events > 48 hours.}\]

\[\text{\(\Delta\) Images: Secco G et al. Time-related changes in neointimal tissue coverage following a new generation SES implantation: an OCT observational study. Presented at: EuroPCR, May 20, 2014; Paris, France.}\]

**Small Vessels. Ultrathin Struts. Big Difference.**

Small vessel subgroup analysis (n = 1,504) of a large scale all-comers BIO-RESORT (n = 3,514) trial.

Fewer repeat target lesion revascularizations (TLR) compared to Resolute Integrity at 36 months.\(^9\)

**Lower revascularization rates in the 3\(^{rd}\) year**

\[\begin{align*}
\text{BIO-RESORT}^9 & \quad \text{small vessel sub-group} \\
\text{BIOFLOW-V}^7 & \quad \text{lower TLR rate vs. Resolute Integrity} \\
\text{60\%} & \quad (p = 0.009) \\
\text{52\%} & \quad (p = 0.009) \\
\end{align*}\]

**Ultrathin, ultra effective**

Ultrathin vs. thin strut DES in a large scale meta-analysis including more than 11,000 patients\(^11\)

\[\text{16\% reduction in TLF rate at 12m (RR=0.84; 95% CI 0.72-0.99)}\]
**Better push**

Transmits up to 72% more force from hub to tip\(^3\)

```
Orsiro   BIOTRONIK
Resolute Onyx  Medtronic
Synergy  Boston Scientific
Xience Sierra  Abbott
```

**Excellent deliverability**

Improved acute performance – up to 7% lower crossing profile\(^1\)

```
Orsiro   BIOTRONIK
Resolute Onyx  Medtronic
Synergy  Boston Scientific
Xience Sierra  Abbott
```

"Low profile and great deliverability coupled with superb clinical outcomes is a game-changer. In the current era of coronary stents, thinner struts are better and thinnest might be best."

**Dr. Dean Kereiakes**

**BIOFLOW-V Site Principal Investigator**

---


Orsiro is a trademark or registered trademark of the BIOTRONIK Group of Companies.

Synergy is a trademark or registered trademark of the Boston Scientific Group of Companies. Resolute, Integrity, Resolute Onyx and Resolute Onyx are trademarks or registered trademarks of the Medtronic Group of Companies. Xience Prime and Xience Sierra are trademarks or registered trademarks of the Abbott Group of Companies.