

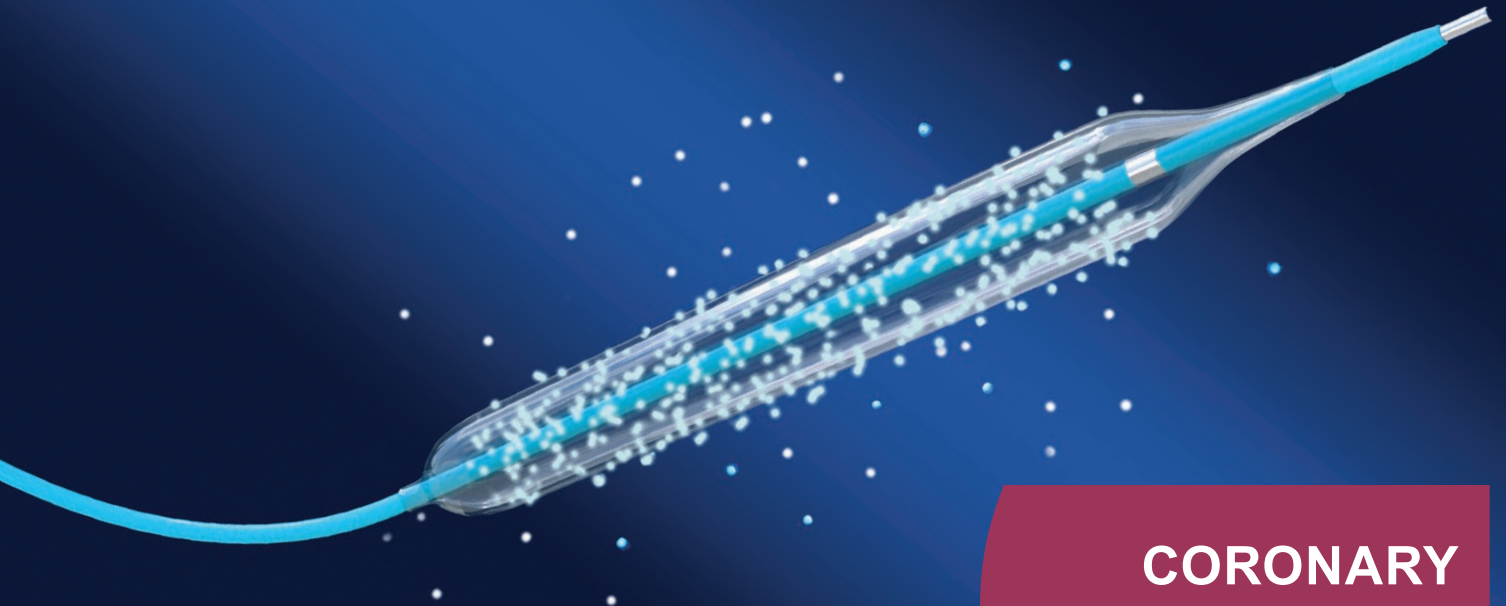


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SUPPORT C

Paclitaxel Eluting PTCA Balloon Catheter

- **Precise Deliverability**
- **Predictable Coating**
- **Prompt and Safe Drug Transfer**
- **Persistent Tissue Absorption**

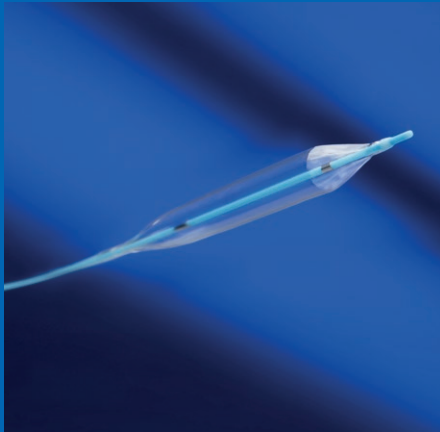


**CORONARY
INTERVENTION**

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SUPPORT C

Paclitaxel Eluting PTCA Balloon Catheter



- Proven eucaVI catheter technology
- Ultra low profile (< 1 mm) – 5 F guiding catheter compatibility
- Designed to cross even challenging lesions
- Sensitive push transfer due to balanced distal part and special transition zone between hypotube and distal part
- Hydrophilic coating on distal shaft

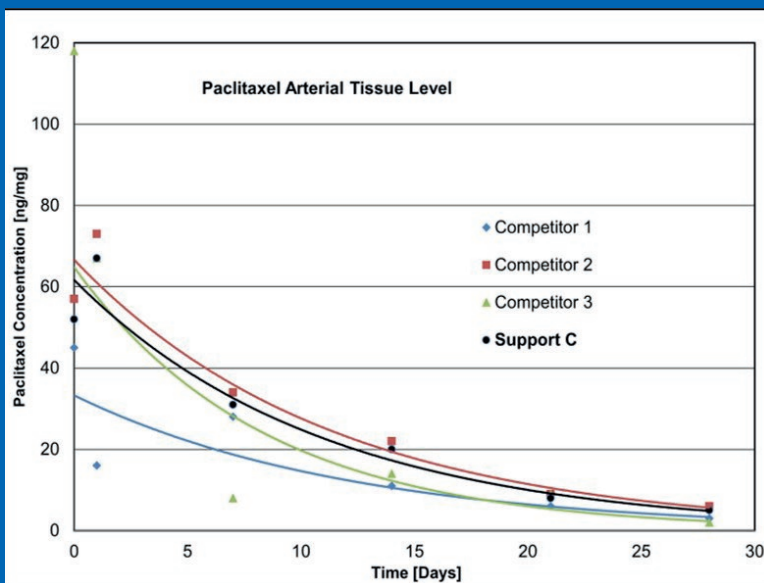
Precise Deliverability

Precise

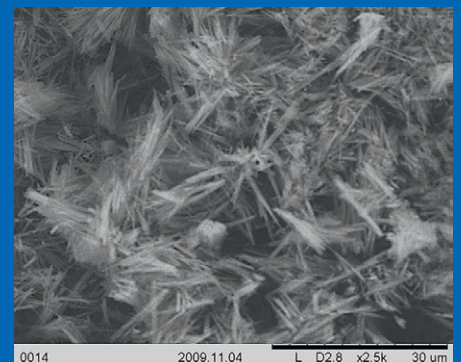
4F
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Persistent Tissue Absorption

Persistent



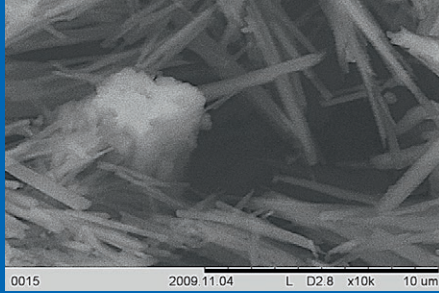
Needle like microcrystalline Paclitaxel particles act as sustained reservoirs which leads to a better tissue absorption and a reliable tissue level of several days



Needle like paclitaxel structure

SUPPORT C

- Precise deliverability
- Predictable coating
- Prompt and safe drug transfer
- Persistent tissue absorption

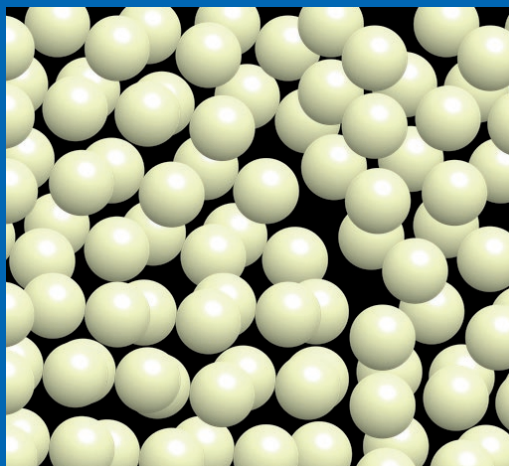


- Using the clinical proven Paclitaxel/BTHC concept
- Safe Paclitaxel dosis of $3 \mu\text{g}/\text{mm}^2$
- Highly biocompatible excipient BTHC (Butyryl-Tri-Hexyl Citrate) rapidly metabolizes by the body to citric acid and alcohol
- BTHC transforms the pure cristalline Paclitaxel structure into an absorbable microcrystalline therapeutic

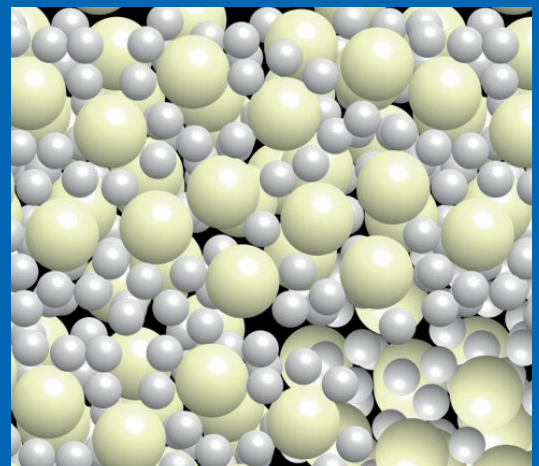
Predictable Coating

Prompt and Safe Drug Transfer

Flexible drug carrier matrix (BTHC) keeps the drug safe on the balloon during transport to the target lesion site and deployment. BTHC acts as a gel coating before it is metabolized fixing the microcrystalline Paclitaxel on the vessel wall. No accumulation of wash-out particles due to fast metabolization – low risk of embolization.



Inflexible pure Paclitaxel cristalline structure



Flexible drug carrier matrix Paclitaxel and BTHC

Predictable

Support
Technology

Prompt

SUPPORT C

Paclitaxel Eluting PTCA Balloon Catheter

36 MONTHS SHELF LIFE

CATHETER SPECIFICATIONS

| | | |
|----------------------------|--|-------------------------------------|
| Usable catheter length | 138 cm | |
| Length of guidewire lumen | 27 cm | |
| Material | Balloon | Proprietary polyamide compound |
| | Distal shaft | Polyamide, multilayer tube |
| | Proximal shaft | Stainless steel, PTFE coating |
| Shaft size | Proximal | 1.9F (0.63 mm) |
| | Distal | 2.8F (0.93 mm) – hydrophilic coated |
| Balloon wrapping | Tri-fold | |
| Marker bands | Two embedded platinum-iridium markers | |
| Tip entry profile | 0.017" (0.43 mm) | |
| Maximum guidewire diameter | 0.014" (0.36 mm) | |
| Recommended guide catheter | 5F - Minimum inner diameter 0.056" (1.42 mm) | |
| Recommended inflation time | At least 30 seconds | |

COATING SPECIFICATIONS

| | |
|---------------------------|--|
| Drug | Paclitaxel |
| Drug dose | 3.0 µg/mm ² |
| Molecular transfer matrix | Butyryl-Tri-Hexyl Citrate (BTHC) |
| Coating area | Cylindrical and tapered section of the balloon |

COMPLIANCE CHART

| Pressure [MPa/bar] | Balloon-Ø [mm] | | | | | | | |
|--------------------|----------------|------|------|------|----------------------|------|---------------|------|
| | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.50 | 4.00 |
| 0.7/7 | 2.00 | 2.25 | 2.50 | 2.75 | 3.00 | 3.25 | 3.50 | 4.00 |
| 0.8/8 | 2.05 | 2.30 | 2.53 | 2.79 | 3.03 | 3.29 | 3.55 | 4.06 |
| 0.9/9 | 2.09 | 2.35 | 2.57 | 2.83 | 3.07 | 3.33 | 3.59 | 4.12 |
| 1.0/10 | 2.14 | 2.40 | 2.60 | 2.87 | 3.10 | 3.37 | 3.64 | 4.18 |
| 1.1/11 | 2.18 | 2.45 | 2.63 | 2.91 | 3.14 | 3.41 | 3.68 | 4.24 |
| 1.2/12 | 2.23 | 2.50 | 2.67 | 2.94 | 3.17 | 3.45 | 3.73 | 4.29 |
| 1.3/13 | 2.27 | 2.54 | 2.70 | 2.98 | 3.20 | 3.49 | 3.77 | – |
| Nominal Pressure | 0.7 MPa/7 bar | | | | Rated burst pressure | | Do not exceed | |

ORDER INFORMATION

| Balloon-Ø | Balloon length | | | | |
|-----------|----------------|----------|----------|----------|----------|
| | 10 mm | 15 mm | 20 mm | 25 mm | 30 mm |
| 2.00 mm | SUC20010 | SUC20015 | SUC20020 | SUC20025 | SUC20030 |
| 2.25 mm | SUC22510 | SUC22515 | SUC22520 | SUC22525 | SUC22530 |
| 2.50 mm | SUC25010 | SUC25015 | SUC25020 | SUC25025 | SUC25030 |
| 2.75 mm | SUC27510 | SUC27515 | SUC27520 | SUC27525 | SUC27530 |
| 3.00 mm | SUC30010 | SUC30015 | SUC30020 | SUC30025 | SUC30030 |
| 3.25 mm | SUC32510 | SUC32515 | SUC32520 | SUC32525 | SUC32530 |
| 3.50 mm | SUC35010 | SUC35015 | SUC35020 | SUC35025 | SUC35030 |
| 4.00 mm | SUC40010 | SUC40015 | SUC40020 | SUC40025 | SUC40030 |



Quality. Made in Germany

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