Endovascular treatment of intracranial aneurysms using the new **Pipeline Flex** Endovascular Device: prospective multi-center study in 25 patients

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Endovascular treatment of intracranial aneurysms using the new Pipeline Flex Endovascular Device: prospective multi-center study in 30 patients

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Consultant of Covidien

Proctor of Pipeline Endovascular Device

Pipeline Flex Clinical Study. Institutional PI (Covidien)

Swift prime trial (Covidien). Institutional Co-PI
Flow Diversion: Pipeline Embolization Device

- One of the most widely used
- 48 strand, (75% chromium–cobalt/25% platinum–tungsten)
- Good **clinical** and **long-term results** in various previous studies (PUFS, IntrePED, etc)
First generation PED

Invitro images from INR Unit-Hospital Clínico de Valladolid, Spain

Mario Martínez-Galdámez
PED-LIMITATIONS

- Learning curve: predictive factor for the procedure-related complication rate.
- Resheathing capture coil in small/tortuous anatomoties /telescopying
- No repositioning: Proximal migration or poor expansion
- Sacrifice of an artery or removal by ‘corking’ or ‘pseudocorking’ techniques.
- Distal tip: 0.016 inch. Distal perforation
First generation
Technical complications
PED FLEX: CE mark April 2014

Previous generation PED

PED Flex

Invitro images from INR Unit-Hospital Clínico de Valladolid, Spain
PED Flex

- **Same braid/implant** (clinically-proven)

48 strand, (75% chromium–cobalt/25% platinum–tungsten)

**New delivery system:**

- **Instant release.** Teflon flaps (no capture coil, no “cigar”)

- **Softer distal tip:** (soft hydrophilic 0.012. Tip angle of 55°)

- **Reseathable:** precision (no return-marker)

- **Trackable through tortuosity:** distal navigability (larger pusher)
# Preliminary experience with the Pipeline Flex Embolization Device: technical note

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## Table 1: Aneurysms and devices characteristics, intraprocedural details and clinical status

<table>
<thead>
<tr>
<th>Case</th>
<th>Aneurysm location</th>
<th>Aneurysm type/status</th>
<th>Max diameter (mm)</th>
<th>No of PED Flex</th>
<th>Device size (mm)</th>
<th>Resheath times</th>
<th>Intraprocedural complications</th>
<th>mRS prior</th>
<th>mRS at discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Carotid cave</td>
<td>Saccular unruptured</td>
<td>4</td>
<td>1</td>
<td>4×16</td>
<td>1</td>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Hypophyseal</td>
<td>Saccular unruptured</td>
<td>6</td>
<td>1</td>
<td>4×14</td>
<td>0</td>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>V4 segment</td>
<td>Dissecting unruptured</td>
<td>8</td>
<td>2</td>
<td>3.75×14 5×14</td>
<td>0</td>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Cavernous</td>
<td>Saccular unruptured</td>
<td>8</td>
<td>1</td>
<td>4.5×20</td>
<td>1</td>
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<td>0</td>
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<tr>
<td>5</td>
<td>Supradinoid</td>
<td>Dissecting unruptured</td>
<td>30</td>
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<td>3.75×20 5×16</td>
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<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Paraophthalmic</td>
<td>Saccular recanalized</td>
<td>13</td>
<td>1</td>
<td>4.5×20</td>
<td>0</td>
<td>None</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

mRS, modified Rankin scale; PED, Pipeline Embolization Device.
Precise deployment
Figure 2  In vitro distal end opening test explaining the ‘inverting flaps maneuver’. (A) The implant opens instantly but sometimes the flaps (white arrows) do not open fully at the distal end of the device. (B) By resheathing the microcatheter, the flaps are displaced in an inverted fashion. (C) Unsheathing again allows full opening with perfect wall apposition.

“PED FLEX multicenter experience”

- May-September 2014:
  - 30 consecutive cases. All unruptured
- Objective: intra/periprocedural analysis
- 5 centers in Spain

- Incidental: 60%
- Mass effect: 20%
- Ischemic: 4%
- Recanalized: 16%
- Incidental: 60%
Aneurysm location

- Cavernous/Paraophtalmic: 16
- Supraclinoid/carotid cave/hypophyseal: 4
- Coroidal/Pcom: 4
- MCA: 4
- Posterior circulation: 2
Procedures

- Double antiagreggation (at least 5 days)
- Verify-now test in: 19 (63%) . No tested: 11 (37%)
- Good responders 16, poor 0 , hyper 3 (half-dose)
- Triaxial access all the 30 cases
- Days in Hospital: average 4 days
Opening

- Instant, fully: 20 cases (67%)
- Partial: 10 (33%) (fully after resheathing)

Resheathing

- Resheath: 15 cases (50%)
  - For improve aposition: 10 cases
  - For repositioning (proximal migration): 5 cases

- No twists, no removals.
- Flaps slight friction/resistance when recapture: 5 cases
Number of devices

1 Ped flex: 23 (77%)

2 Ped flex: 6. Criteria: mismatch in arterial diameter

No telescoping devices due to malposition

4 Ped flex: 1: Large fusiform ICA aneurysm
Safety of the New delivery system

- Clinical Complications: Neurological deficit
- **Major event:** 1 patient: small internal capsule infarct (3%)
- No minor events (0%)
- Mortality (0%)
- Thromboembolic events: 0%
- Intra/peri-procedural aneurysm rupture: 0%
Conclusions

- The PED Flex device allows more **precise** and **controlled** deployment than the current PED device.
- The new delivery system does not increase the intra/periprocedural complications rate.
- We did not find Teflon flaps detachment nor complications related to them.
- **Reseath & Reposition**: less devices, then less potential complications, less radiation, more cost-efficient.
- Softer distal tip: could avoid potential complications