

New items are in **bold**.

STUDY	SAMPLE SIZE	SPONSOR	STUDY DESIGN	LOCATION	RESULTS	STATUS	
Paclitaxel, Taxol (antineoplastic)							
ELUTES (dose-finding study)	n=192; 9 clinical centers	Cook	V-Flex Plus PTX vs bare stent		<i>De novo</i> lesions in native coronaries	Six-month binary restenosis: 3.1% highest-dose, 20.0% lowest-dose, 20.6% control. Twelve-month TLR: 5% highest dose vs 16% in control. No late thrombosis, death, or MI (presented at AHA 11/02).	CE Mark approval 9/02 for V-Flex Plus PTX stent. This stent will not be introduced in the US.
In-stent ELUTES	n=600 (planned); 22 European centers	Cook	Three treatment groups using low-dose and high-dose V-Flex Plus PTX stent vs bare stent		In-stent restenosis	No results available.	Results to be used in request for additional indications for V-Flex Plus PTX stent.
TAXUS II (safety and efficacy)	n=536; 38 centers in 15 countries	Boston Scientific	1.0 µg/mm ² slow-release and moderate-release drug-eluting NIR stent vs bare NIR stent		<i>De novo</i> lesions in native coronaries	12-month MACE: 10.9% SR, 9.9% MR (vs 21.7% in combined controls; 1 stent thrombosis in SR, 1 in MR, 0 in controls).	Results published in <i>Circulation</i> (2003;108:788-94).
TAXUS III (single-arm registry)	n=30; 2 European centers	Boston Scientific	NIR drug-eluting stent		In-stent restenosis	Six-month binary restenosis: 16%; MACE: 28.6%.	Results published in <i>Circulation</i> (2003;107:559-564).
TAXUS IV (pivotal study)	n=1,326; 74 US centers	Boston Scientific	TAXUS stent vs Express2 uncoated stent		<i>De novo</i> lesions in native coronaries	TLR at 9 and 12 mos: 3% and 4.2% for TAXUS vs 11.3% and 14.7% for controls. 9-mo TVR: 4.7% for TAXUS vs 12.0% for controls (61% relative RR). 9- and 12-mo MACE: 8.5% and 10.6% for TAXUS vs 15% and 19.8% for controls. Stent thrombosis: 0.6% vs 0.8%.	Taxus stent approved in Canada 9/03. FDA Panel recommends approval 11/03. Results published in the <i>New England Journal of Medicine</i> (2004;350:221-231).
TAXUS V	n=1,100 planned; up to 70 clinical centers	Boston Scientific	TAXUS stent vs bare Express stent		High-risk patients with long <i>de novo</i> lesions (<4.0 mm) in native coronaries	No results available.	Enrollment anticipated to begin in early 2003.
TAXUS VI	n=448	Boston Scientific	Moderate-release drug-eluting Express stent vs bare Express stent		High-risk patients with long <i>de novo</i> lesions (18 mm-40 mm) in native coronaries	No differences in postprocedure OCA between groups. 30-day in-hosp MACE: 4.8% group A, 6.8% group B; out-of-hosp MACE: 0.9% and 0.5%, respectively. Stent thrombosis: A=1, B=2 at 30 days.	Long-term and 9-month IVUS and angiographic results to be presented at EuroPCR 2004.
DELIVER	n=1,043	Guidant	3.0 µg/mm ² drug-eluting Achieve stent vs bare Penta stent		<i>De novo</i> lesions in native coronaries	30-day MACE: 0.8%. Group A, enrolling 524 patients, reported a 1.2% MACE; group B, enrolling 519 patients, reported 0.4% MACE.	Enrollment and follow-up completed.
DELIVER II	n=1,533; 76 non-US clinical sites	Guidant	Achieve stent system		High-risk patients with <i>de novo</i> lesions and ISR coronaries	6-month TLR: 10.5%; 6-month MACE: 15.7%.	Results presented at ESC 9/03.
Rapamycin, sirolimus, Rapamune (macrocyclic lactone, immunosuppressant)							
SIRIUS	n=1,101; 53 US sites	Cordis (J&J)	CYPHER stent vs Bx Velocity bare stent		<i>De novo</i> lesions in native coronaries; lesions 2.5 mm-3.5 mm in length	8-mo restenosis: 32% for CYPHER vs 35.4% for controls. 2-year TLR and TVF: 6.3% and 13.0% for CYPHER vs 21.0% and 26.6% in control. 2-yr MACE: 10.9% vs 24.2%, respectively. Stent thrombosis: 0.6% CYPHER, 0.8% controls.	CYPHER received FDA approval 4/03. SIRIUS results published in <i>New England Journal of Medicine</i> (2003;349:1315-1323). 2-yr results presented at AHA 11/03.
E-SIRIUS	n=353 in Europe	Cordis (J&J)	CYPHER stent vs. Bx Velocity stent. Direct stenting (DS) option left to investigator's discretion.		<i>De novo</i> lesions in native coronaries	DS done on 26%. 9-mo MACE: reduced 79% compared to DS control vs 60% in predilat group (results maintained at 1-year). In-lesion restenosis: CYPHER+DS=2.4% and CYPHER+predilat=7.0%.	Results presented at ESC 9/03; published in <i>Lancet</i> . 2003;362(9390):1093-1099. Results updated at AHA 11/03.
CSIRIUS	n=102 in Canada	Cordis (J&J)	CYPHER stent vs Bx Velocity bare stent		<i>De novo</i> lesions in native coronaries	100% reduction in in-stent restenosis at 8 months; 91% reduction in late loss; 64% improvement in minimum lumen diameter.	Results presented at ACC 3/03.
RAVEL	n=238; 19 centers in Europe and Latin America	Cordis (J&J)	CYPHER stent vs Bx Velocity bare stent		<i>De novo</i> lesions in native coronaries; lesions 2.5 mm-3.5 mm in length	Six-month restenosis: 0%. 12-month MACE: 5.8% DES vs 18.6% control group. 24-month reintervention: 2.5% (3 patients); thrombosis: 0% (presented at ACC 3/03).	Trial results published in the <i>New England Journal of Medicine</i> (2002;346:1773-80). CYPHER stent rec'd CE mark approval, 4/02.
SIROCCO I	n=36; 6 sites in Europe and Canada	Cordis (J&J)	Slower-eluting SMART nitinol self-expanding drug-eluting stent and fast-eluting model vs bare SMART stent control		Superficial femoral artery; 7 mm-20 mm in length; max of 3 stents allowed	24-month total restenosis: 40% (slower-eluting) vs 44.4% (fast-eluting) vs 47.1% control. TLR: 0% vs 11.1% vs 5.8%, respectively; 24% overall fracture rate.	Results presented at TCT 9/03.
SIROCCO II	n=57; 6 sites in Europe and Canada	Cordis (J&J)	Slower-eluting SMART nitinol self-expanding drug-eluting stent vs bare SMART stent control		Superficial femoral artery; 7 mm-14.5 mm in length; max of 2 stents allowed	6-month in-stent angio: 0% restenosis in study group; 7.7% control; late loss: 0.38±0.64 vs 0.68±0.97; TVR: 3.4% vs 10.7%; 0 TLRs; 0 thromboses; 6% fracture rate.	Results presented at TCT 9/03.
FIM (feasibility study)	n=45; Sao Paulo, Brazil, and Rotterdam, The Netherlands	Cordis (J&J)	Slow-release and fast-release CYPHER stent		<i>De novo</i> lesions in native coronaries, 3.0 mm-3.5 mm in length	Three-year event-free survival: 93.3%. Neointimal hyperplasia obstruction at 24 months: 9.2% fast-release, 3.3% slow-release (presented at AHA 11/02).	One-year results published in <i>Circulation</i> (2001; 104:2007-2011).
GREAT (safety and efficacy)	n=100; multiple centers in Europe	Cordis (J&J)	Drug-eluting stainless steel balloon-expandable stent vs bare stainless steel balloon-expandable stent		Renal artery stenosis	No results available.	Trial announced 2/03.
Tacrolimus (immunosuppressive macrolide)							
PRESENT I (safety study)	n=22	Abbott Vascular	FlexMaster nanoporous ceramic coated stent		<i>De novo</i> lesions in native coronaries	30-day MACE: 0%. 6-mo MACE 13.6% (all from TLR). In-stent restenosis 19%.	PRESENT III trial currently underway.
Dexamethasone (corticosteroid)							
STRIDE (safety and feasibility study)	n=71; 8 Belgian sites	Abbott Vascular	BiodivYsio phosphorylcholine (PC) drug-eluting 0.5 µg/mm ² dexamethasone Matrix Lo stent		<i>De novo</i> lesions in native coronaries	Six-month MACE: 3.3%. Six-month restenosis: 13.3%. Promising results in patients with UA (presented at ACC 3/02).	Dexamet DES launched in Europe 2/03.
Everolimus (immunosuppressive, antiproliferative)							
FUTURE I (safety study)	n=42, 1 site	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare-metal stent.		<i>De novo</i> lesions in native coronaries ≤18 mm long; diabetics excluded	6-mo angio late loss and restenosis: .11 mm and 0% for DES vs .85 mm and 9.1% for control. No new MACE from 6 to 12 mos, no in-stent binary restenosis at 12 mos, no aneurysms or malapposition.	Results presented at TCT 9/03.
FUTURE II	n=64; 3 sites	Guidant	Champion everolimus-eluting stent with bioabsorbable polymer matrix vs bare metal stent		<i>De novo</i> lesions in native coronaries ≤18 mm in length, diabetics included	6-mo MACE: 4.8% for DES and 17.5% for BMS; TLR: 4.8% vs 15.0%. MLD at 6 months: 2.74 mm vs 2.02 mm; late loss: 0.12 mm vs. 0.85 mm. 94% reduction in neointimal volume by IVUS with DES.	Results presented at TCT 9/03.
SPIRIT FIRST	n=60; multiple European sites	Guidant	MULTI-LINK VISION with durable polymer vs uncoated stent		<i>De novo</i> lesions ≤12 mm; diabetics included	No results available.	First human implant 12/03.
ABT-578 (immunosuppressive, rapamycin analogue)							
ENDEAVOR	n=100 planned; 8 clinical centers in Australia and New Zealand	Medtronic	Endeavor drug-eluting stent (no control group)		<i>De novo</i> lesions in native coronaries; lesions up to 15 mm in length, vessels 3.0 mm-3.5 mm in length	30-day MACE: 1% for study group, 4-month MACE: 2% and in-stent late loss: 0.33 mm. Percent DS reduced from 70.3% preprocedure to 5.4% post-procedure and 14.4% at 4 months.	Results presented at TCT 9/03.
ENDEAVOR II (pivotal study)	n=approx. 1,200; 96 centers in 21 non-US countries	Medtronic	Endeavor drug-eluting stent vs Driver standard stent		<i>De novo</i> lesions in native coronaries; lesions 14.0 mm-27.0 mm in length	No results available.	Enrollment began 7/03. ENDEAVOR III trial to start limited enrollment.