

SITZUNG IV NEUES AUS DER INTERVENTIONSKÜCHE

Extremitäteninterventionen: Möglichkeiten und Perspektiven...



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Radiologische Universitätsklinik Bonn





Extremitäteninterventionen

Möglichkeiten und Perspektiven...

With new devices emerging and clinical experiences continuing to grow, interventionists discuss the ideal applications for current techniques.

CODING & REIMBURSEMENT: CMS SFA UPDATES - TECHNIQUES: REMOTE ENDARTERECTOMY



Experts discuss the latest innovative applications and procedural considerations for these devices.

SPECIAL REPORT: PERSPECTIVES ON RECENT CAS TRIAL DATA



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ilegx annual meeting
Oct 13-14 2009, Munich, Germany
under auspices of DSG (The German Vascular Society)

CIRSE
INTERNATIONAL RADIOLGY
in association with the Cardiovascular and Interventional Radiological Society of Europe and the Society of Interventional Radiology

The website for interventionalists

Search

Interventional News - Latest News
Setback for drug elution in the periphery as STRIDES follows SIROCCO
Fri 25-Sep-2009

Cook launch Europe's first drug-eluting stent for the SFA
Fri 25-Sep-2009

Against the backdrop of the disappointing STRIDES trial data, COOK Medical launched the first drug-eluting stent for use in the superficial femoral artery in Europe.
Fri 25-Sep-2009

Michael Duke presented highly promising registry data out to two years, but this did not include patency as an endpoint which will be available once the results from the US Zilver PTX Registry are presented next year. The Zilver PTX Registry is the largest registry of its kind ever conducted and results indicate that the Zilver PTX stent can effectively bridge the gap between the patient results achieved using open surgical bypass graft procedure.

32nd CHARGING CONVENTION
HOLD THE DATE
10-13 April 2010

Vascular & Endovascular Challenges update

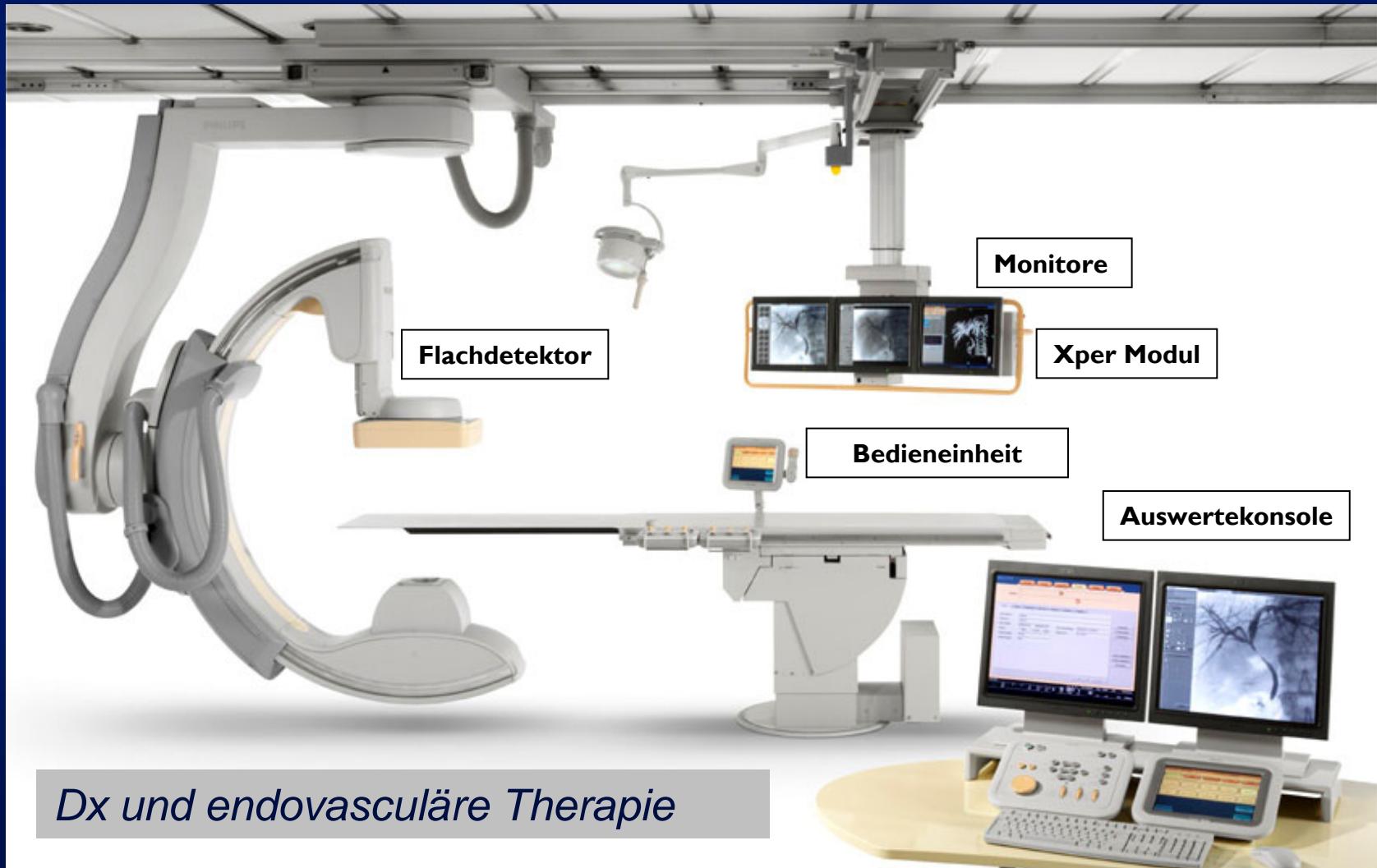
New technologies are emerging, and enhancements have been made to existing devices. Which options are right for your patients?



Extremitäteninterventionen

Möglichkeiten und Perspektiven...

Flachdetektor DSA
Allura Xper FD20C

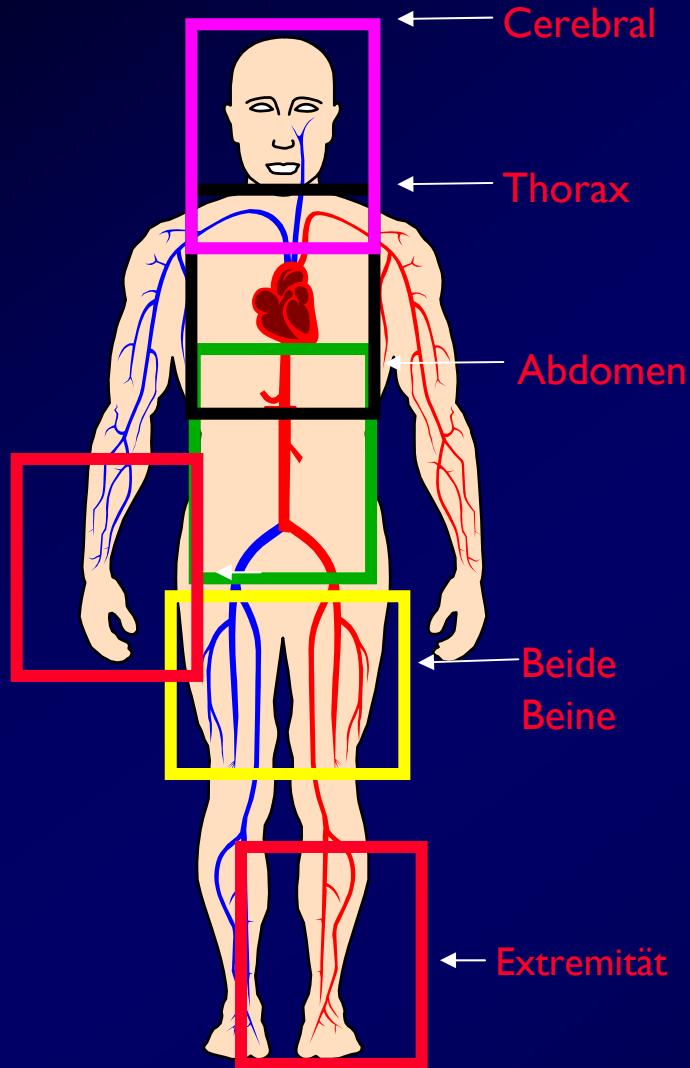




Extremitäteninterventionen

Möglichkeiten und Perspektiven...

Flachdetektor DSA
Allura Xper FD20C



Flachdetektor: 38 cm x 30 cm

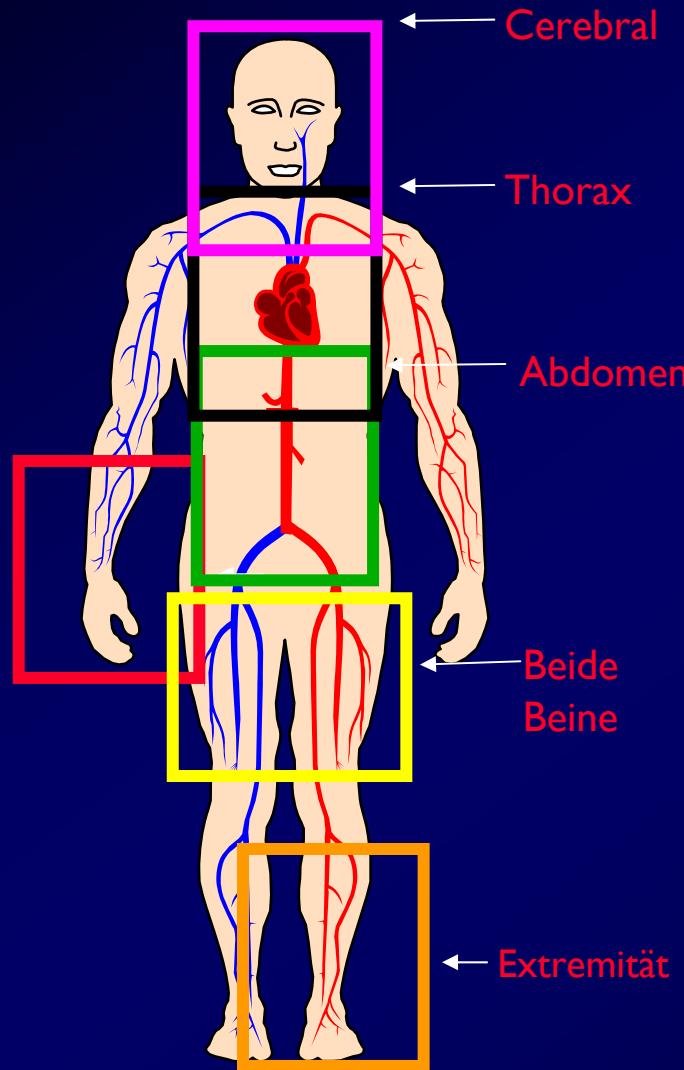
- applikatorischen Freiheitsgrade
- gute Patientenzugänglichkeit
- flexible Positionierung des Detektors
(90° Drehung in 3 Sek.)



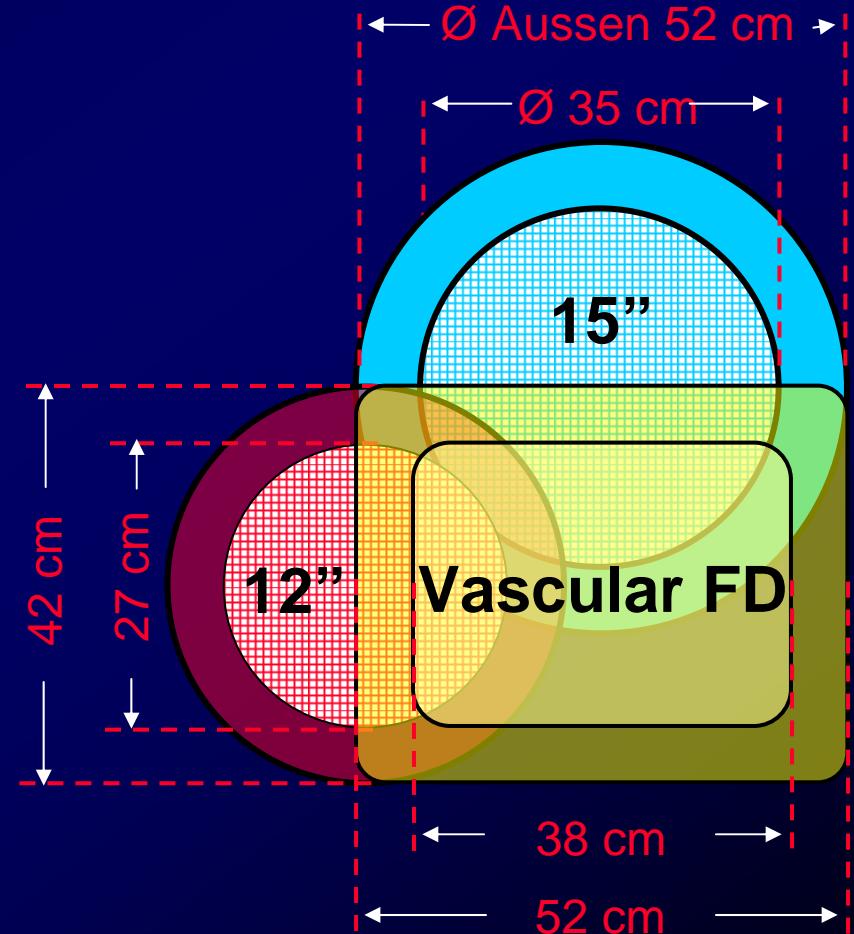
Extremitäteninterventionen

Möglichkeiten und Perspektiven...

Flachdetektor DSA
Allura Xper FD20C



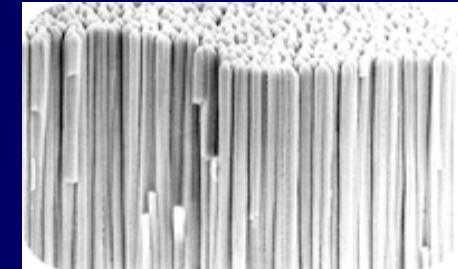
Größenvergleich FD - Bildverstärker





Extremitäteninterventionen

Möglichkeiten und Perspektiven...



Detection Layer

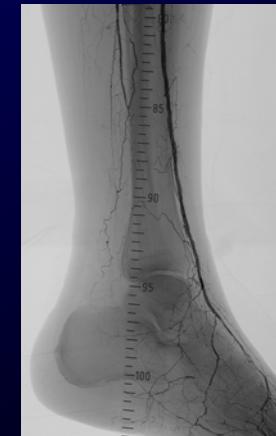
Flachdetektor: Technische Daten

- | | |
|---------------------------|--|
| ➤ Detektorfeld | 38 * 30 [cm] |
| ➤ Zoom-Felder | 30 ² , 22 ² , 16 ² [cm] |
| ➤ Detektor Layer | CsI on Si |
| ➤ Ausgangsmatrix | 2k ² & 2,5k ² , 14 bit |
| ➤ Pixelgröße | 154 x 154 [μm] |
| ➤ Gepulste Durchleuchtung | 15 und 30 [B/s] |



Flachdetektor: → Vorteile

- Hohe Auflösung - Kleine Pixel (154μm) , 5 Millionen Pixeldetektor
- Hoher Kontrast - Dynamikbereich 14 bit
- Kein „Memory-Effekt“ - „Refresh Light „
- Kein Verzeichnung im Bild - 2k² Auflösung

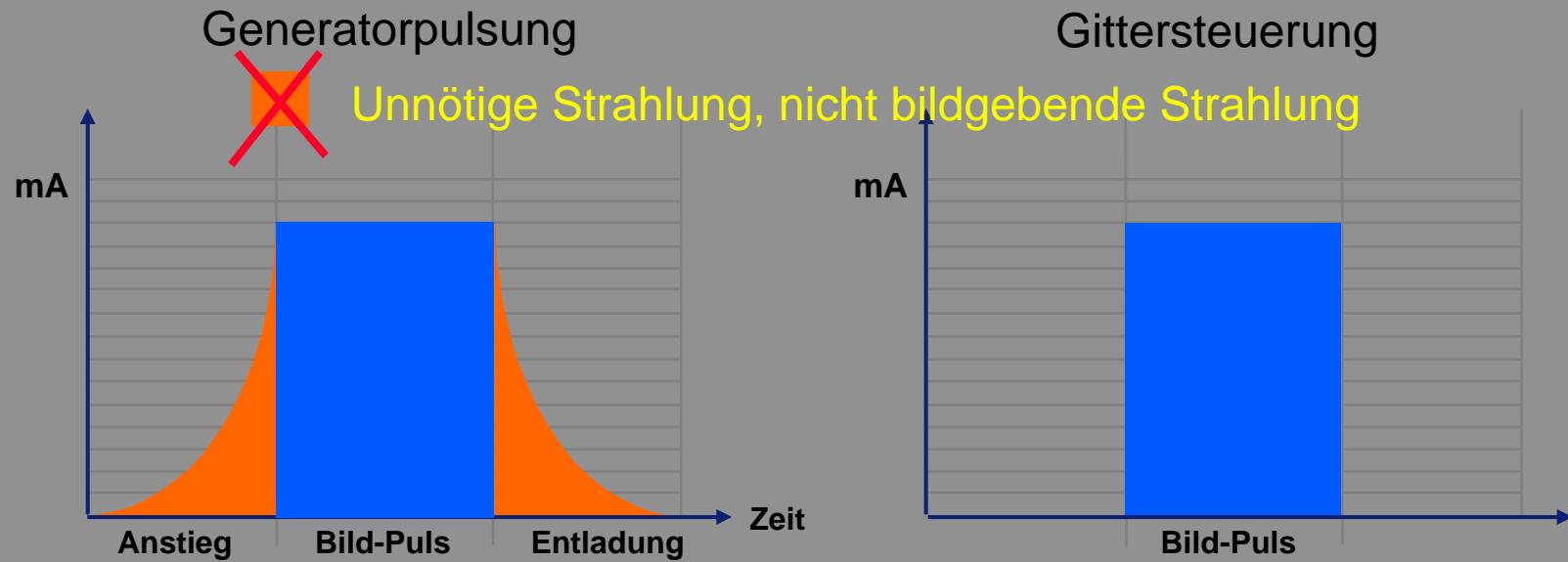
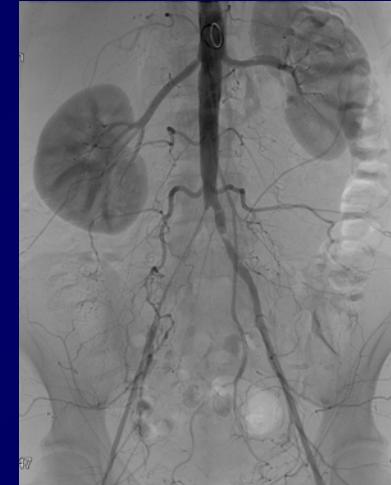




Extremitäteninterventionen

Möglichkeiten und Perspektiven...

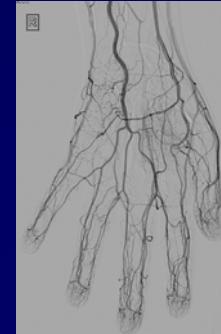
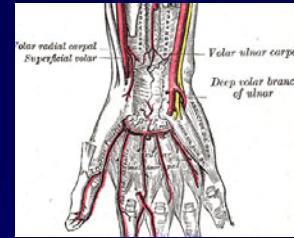
- Dosisreduktion
 - Gittergesteuerte gepulste Durchleuchtung
 - SpectraBeam Zusatzfilterung (bis 1 mm Cu)
 - Einblendung am „Last Image Hold“
 - Speicherung von Durchleuchtungsszenen (bis 10 s)



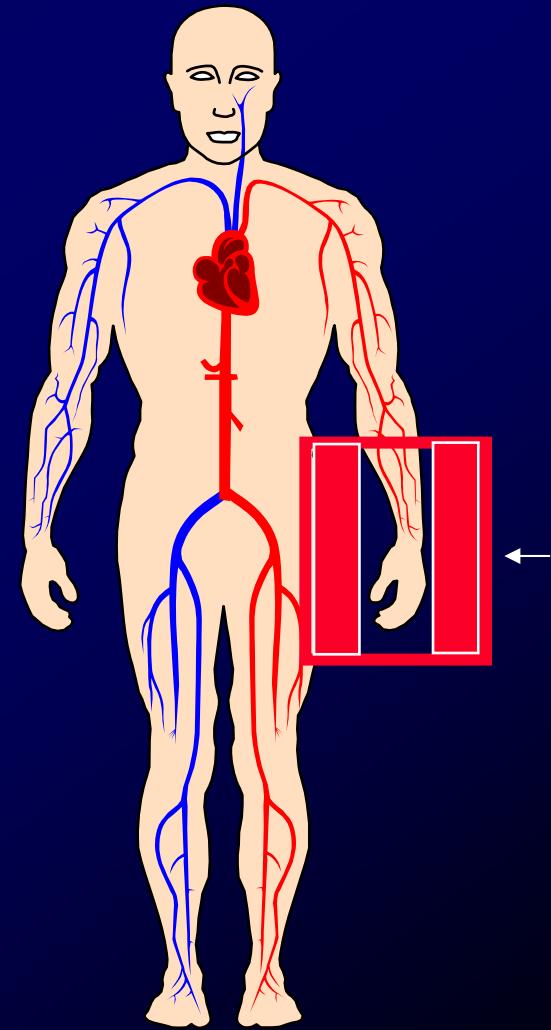
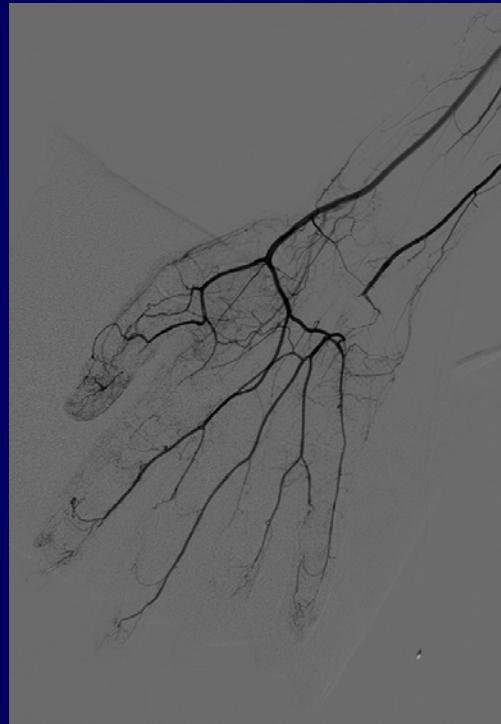


Flachdetektor DSA

Allura Xper FD20C



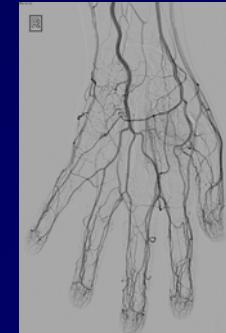
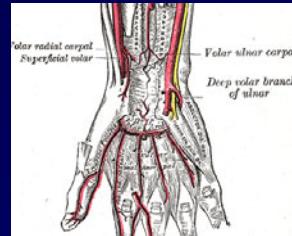
DSA Hand





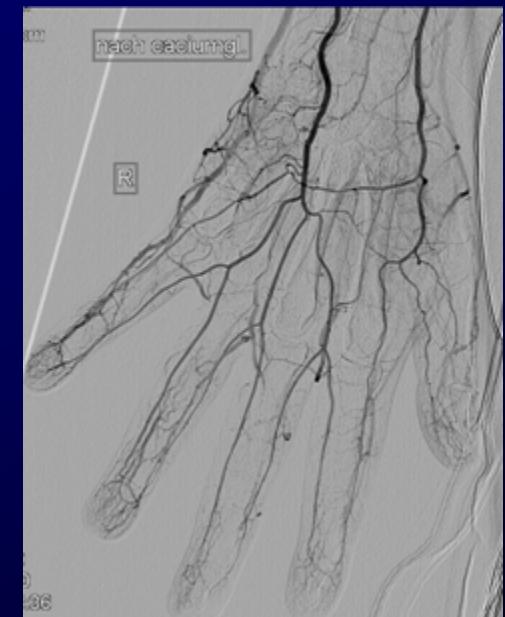
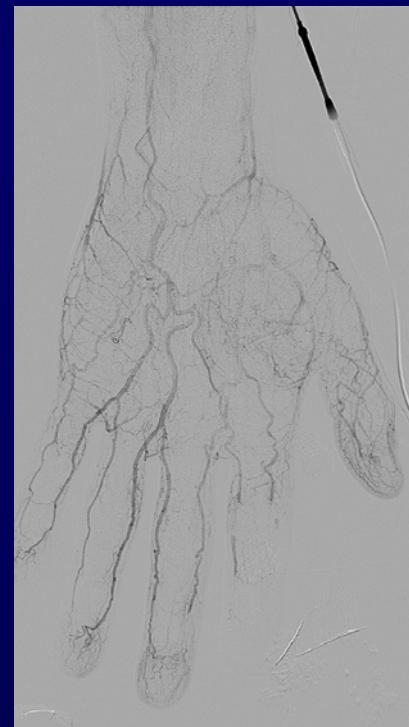
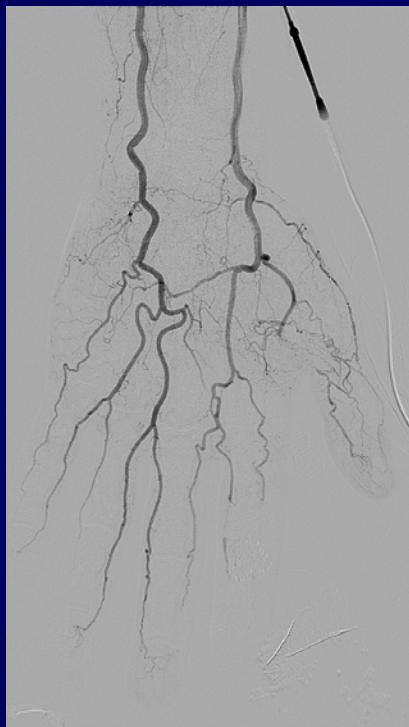
Flachdetektor DSA

Allura Xper FD20C



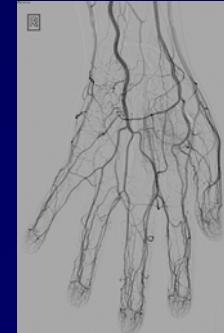
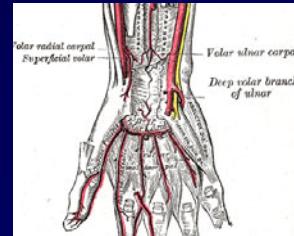
DSA Hand - Vaskulitis

i.a. Calciumgluconat-Therapie
nach Fluorwasserstoffsäure-Exposition

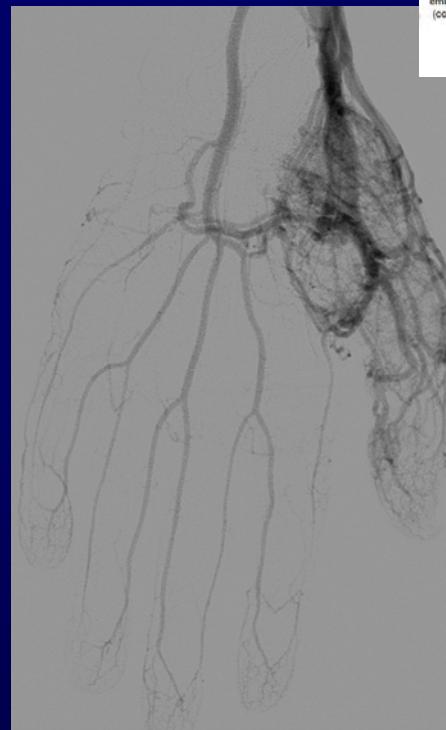
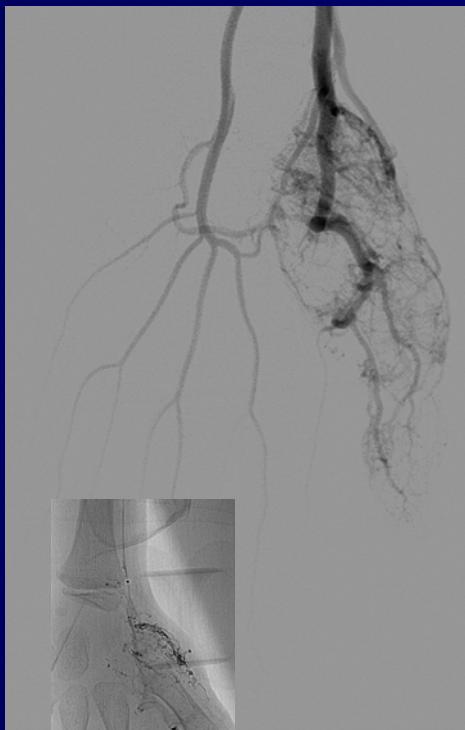
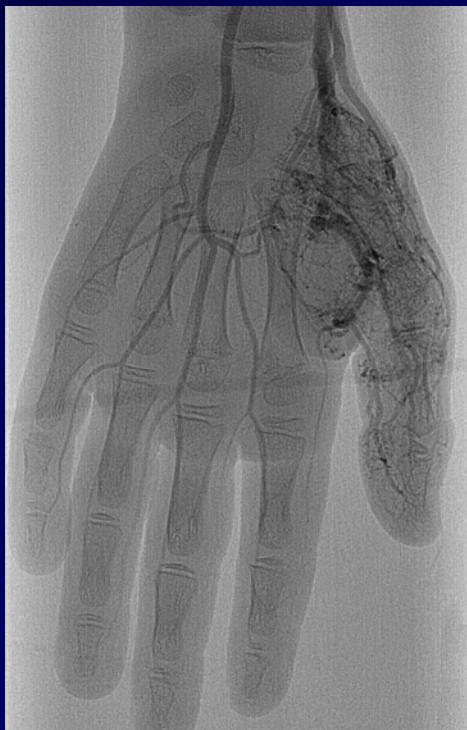
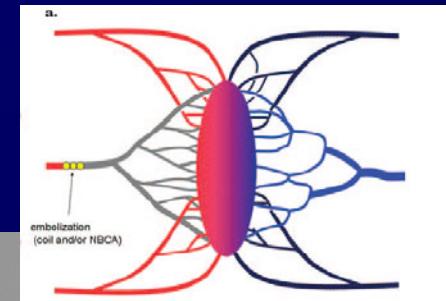


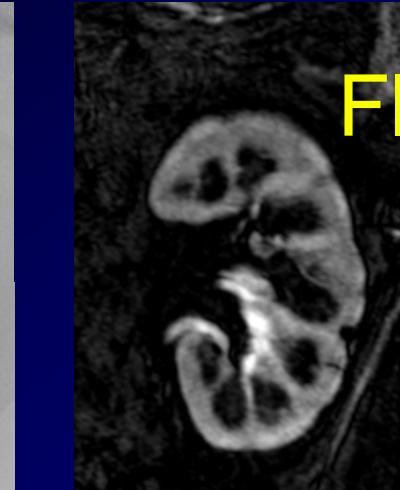


Flachdetektor DSA Allura Xper FD20C



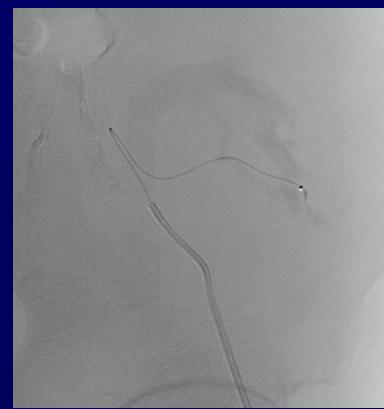
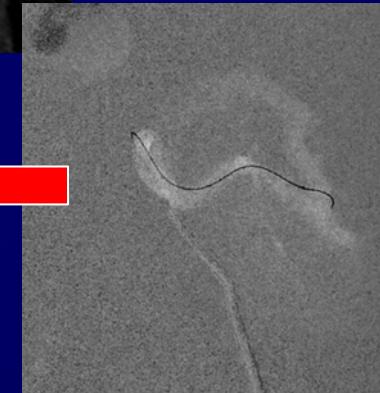
DSA Hand - AVM - Embolisation

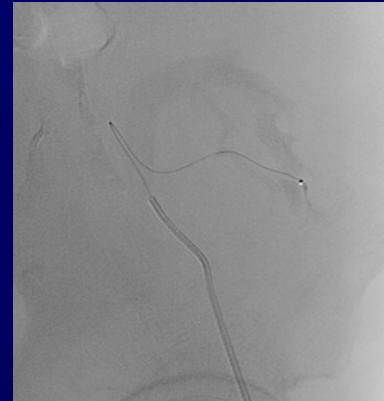
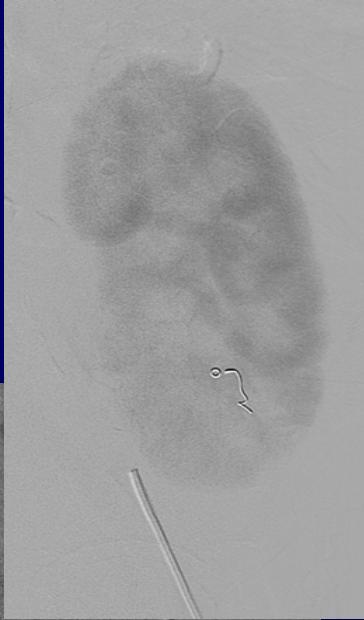
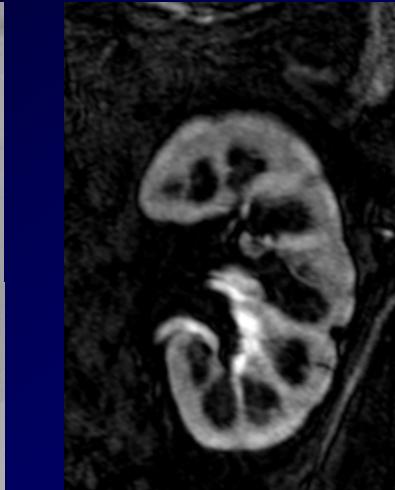




Flachdetektor DSA - Allura Xper FD20C

Fistel-EMBOLisation
Transplantatniere

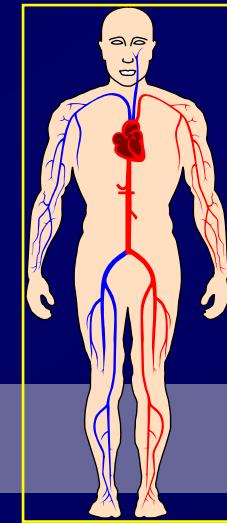
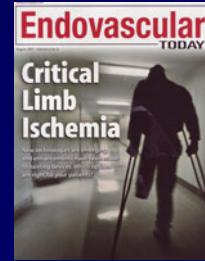






Extremitäteninterventionen

Möglichkeiten und Perspektiven...

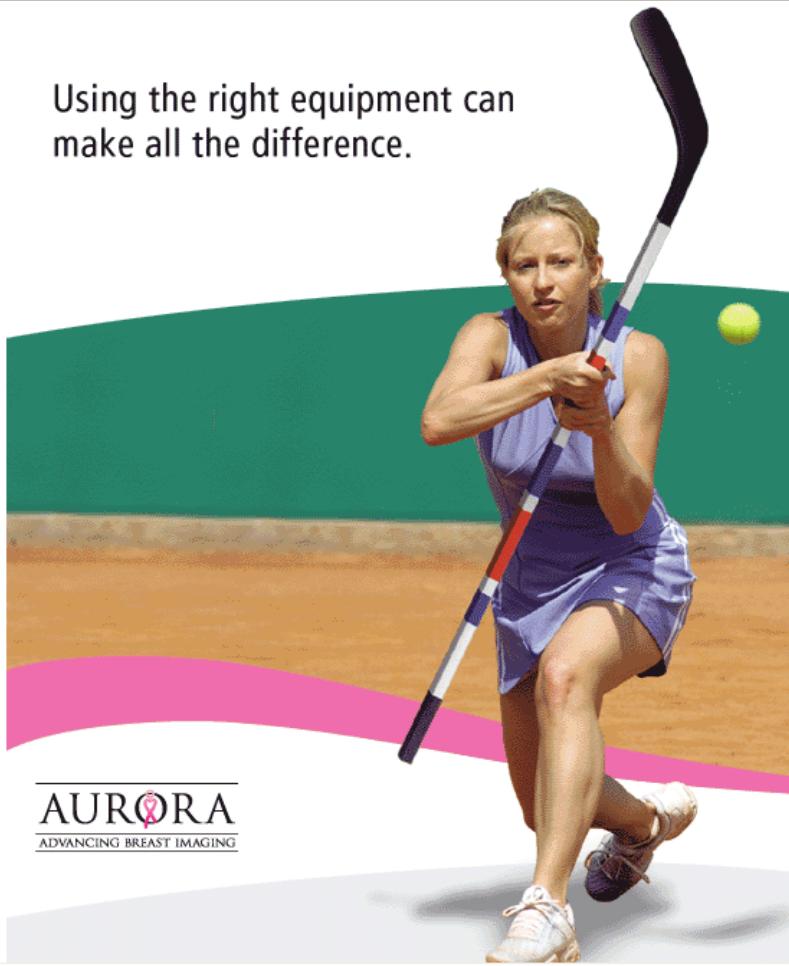


CO₂ Angiographie





Using the right equipment can
make all the difference.



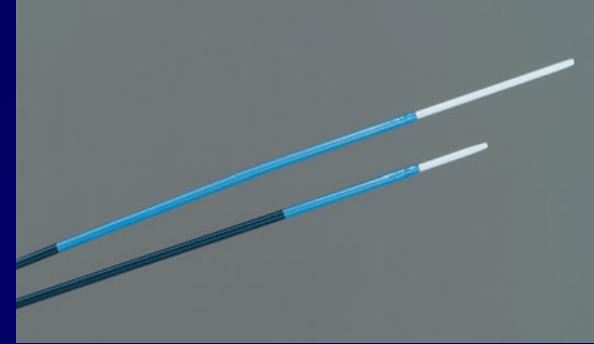
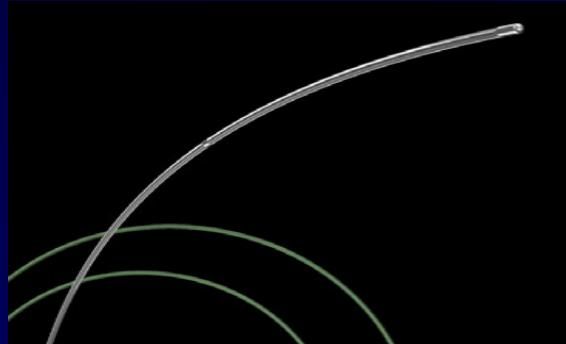
AURORA
ADVANCING BREAST IMAGING



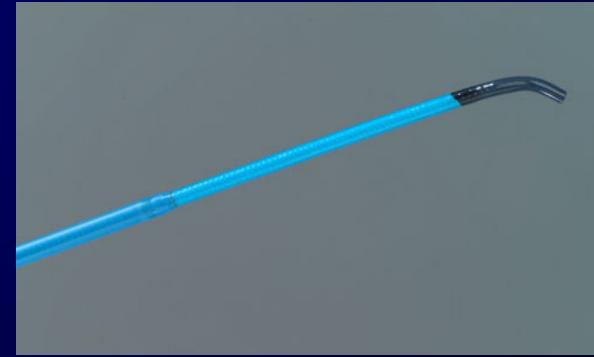
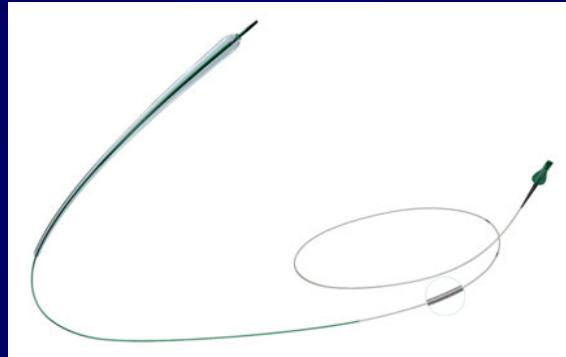
Extremitäteninterventionen

Möglichkeiten und Perspektiven...

Using the right equipment can make all the difference.



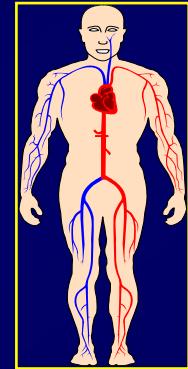
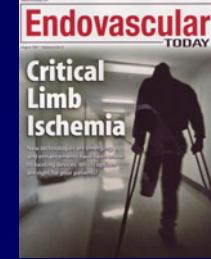
Cook Medical - Infrapopliteal Program



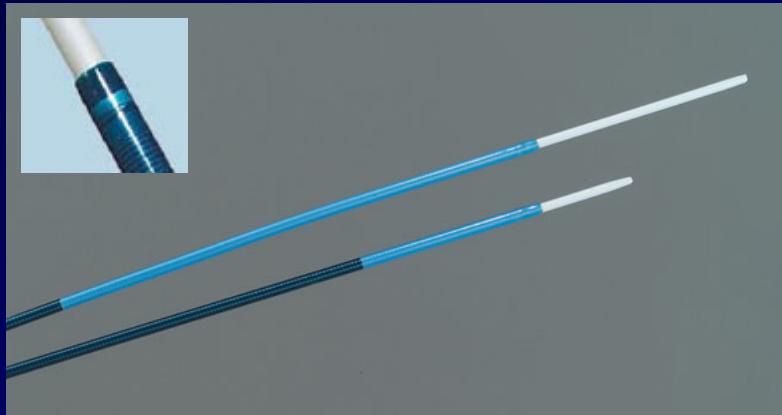


Extremitäteninterventionen

Möglichkeiten und Perspektiven...



Infrapopliteal Sheaths

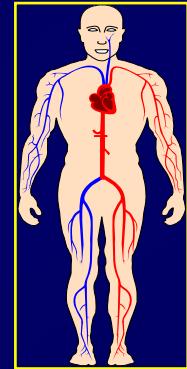
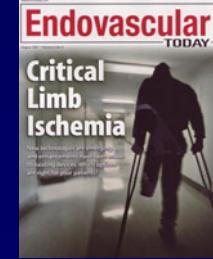


- **4.0F Flexor® Ansel**
- Access infrapopliteal vessels
- Lengths of 90cm and 110cm
- **5.0F Flexor® Ansel**
- Lengths of 90cm and 110cm
- **Shuttle® Tibial**
- Coaxial access system
- Combines Flexor sheath
 - with selective catheter (SCBR)

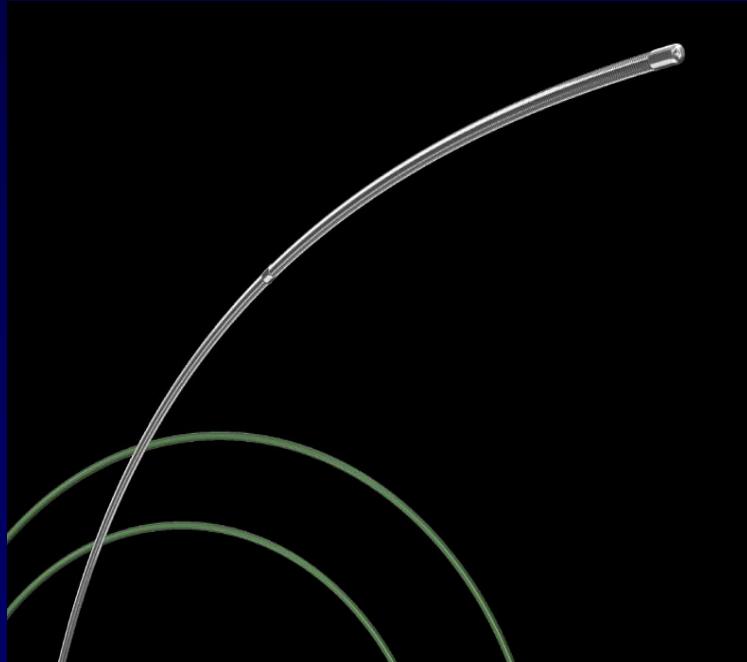


Extremitäteninterventionen

Möglichkeiten und Perspektiven...



Approach® CTO .014 Micro Wires

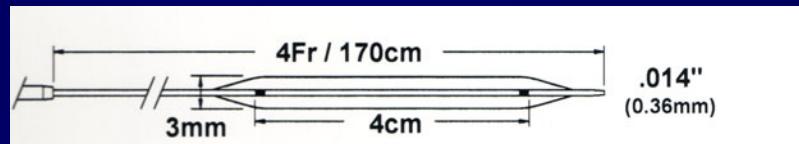
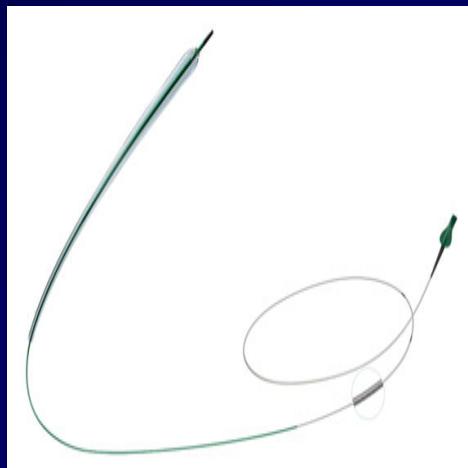
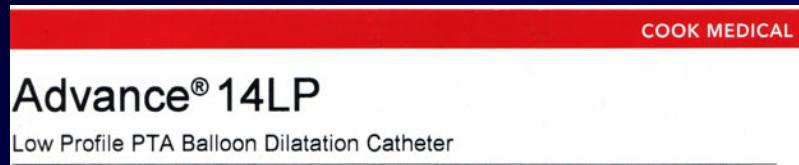
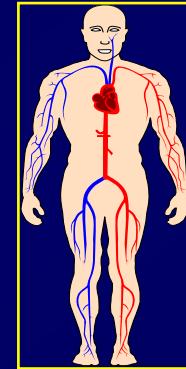
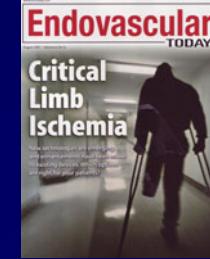


- Lengths: 135, 190 and 300 cm
- A variety of tip loads: 6,12,18 & 25 g
- Shorter taper (10 cm coil, 18 cm taper)
- Stiffer tips for use in highly calcified lesions and occlusions
- Supportive Stainless Steel mandril



Extremitäteninterventionen

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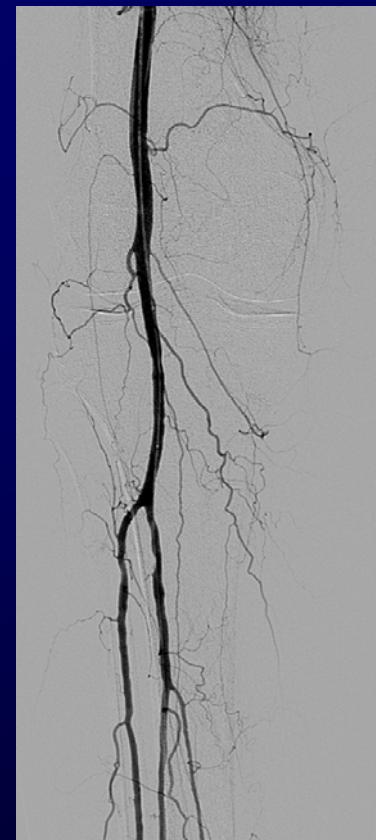
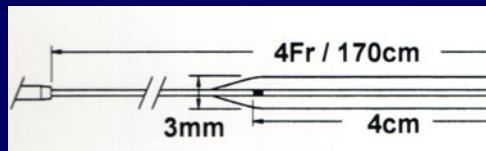
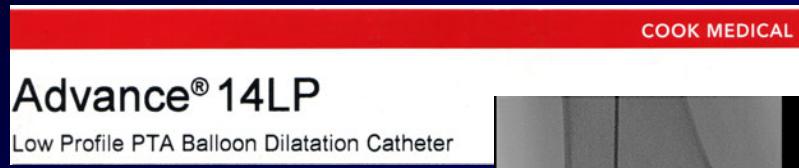
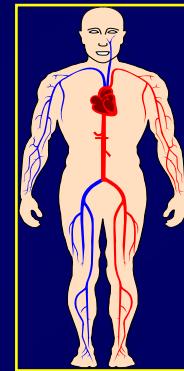
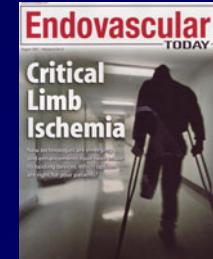


- 4 Fr sheath compatibility
- Diameters: 2-4 mm
- Lengths: 2-20 cm
- 170 cm shaft
- Coiled wire shaft for optimized pushability, trackability and kink resistance
- Hydrophilic coating on distal shaft and balloon



Extremitäteninterventionen

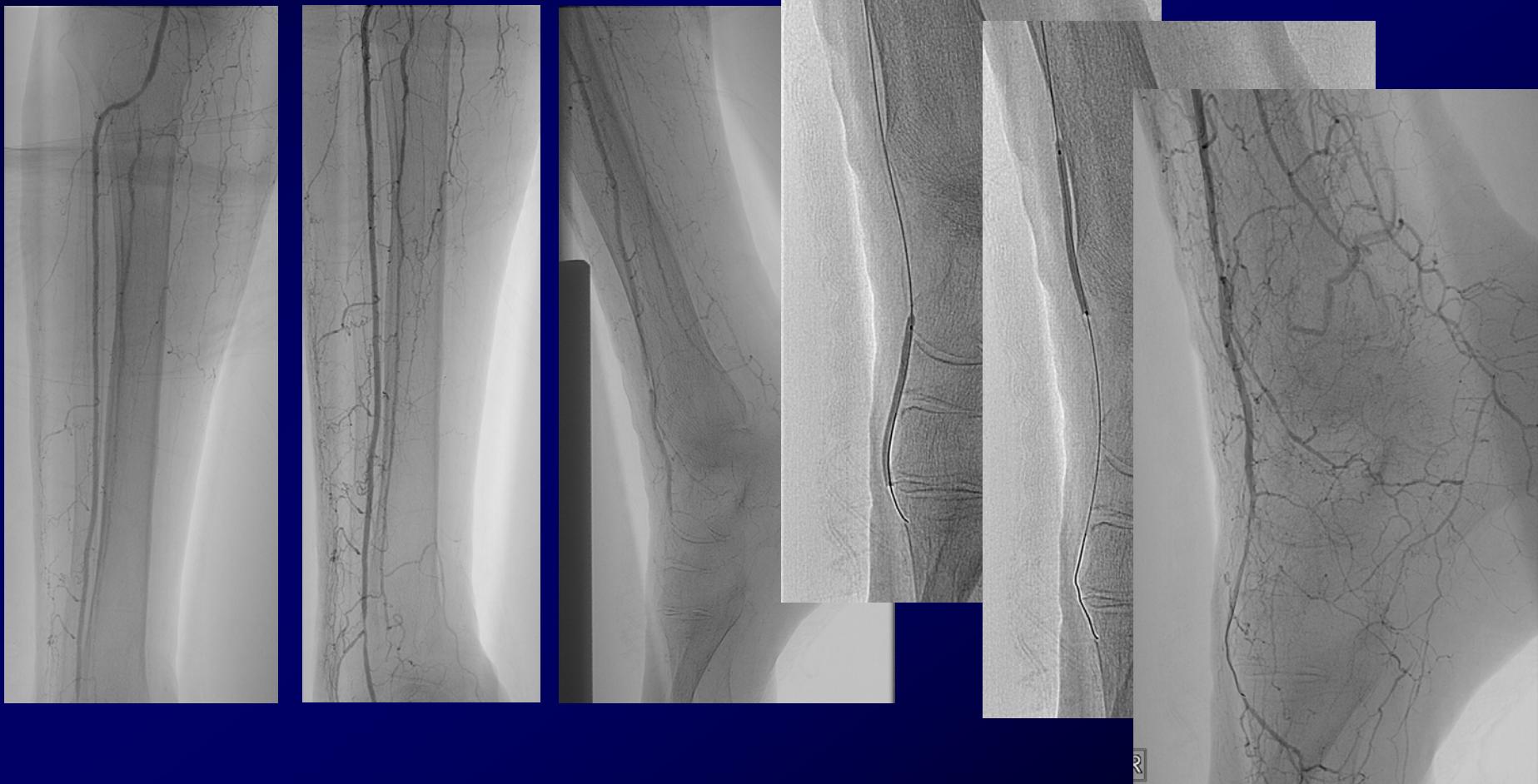
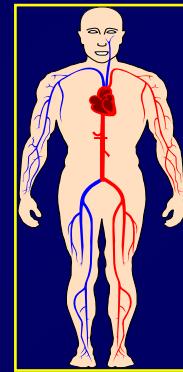
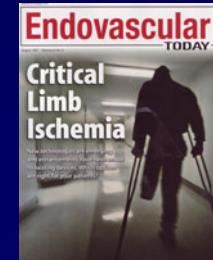
Möglichkeiten und Perspektiven...





Extremitäteninterventionen

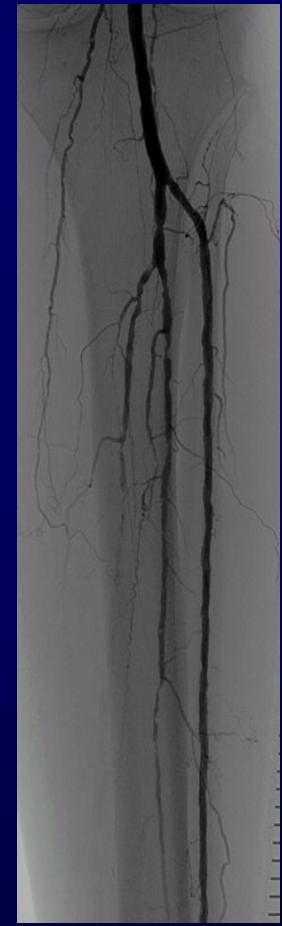
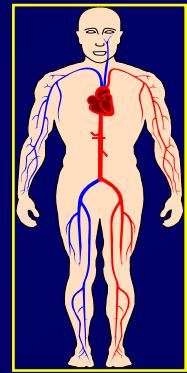
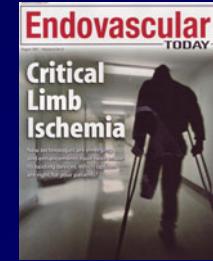
Möglichkeiten und Perspektiven...





Extremitäteninterventionen

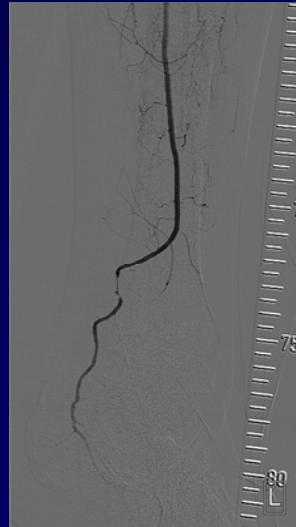
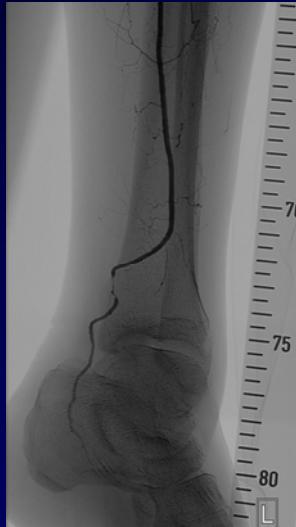
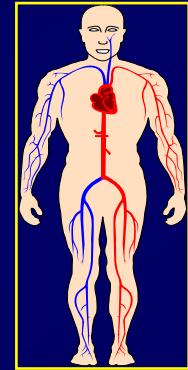
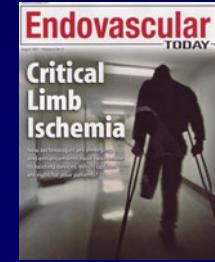
Möglichkeiten und Perspektiven...





Extremitäteninterventionen

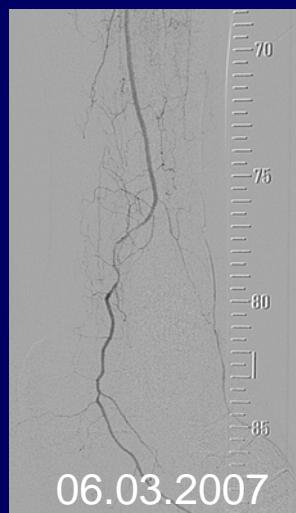
Möglichkeiten und Perspektiven...



PTA 07.11.2006

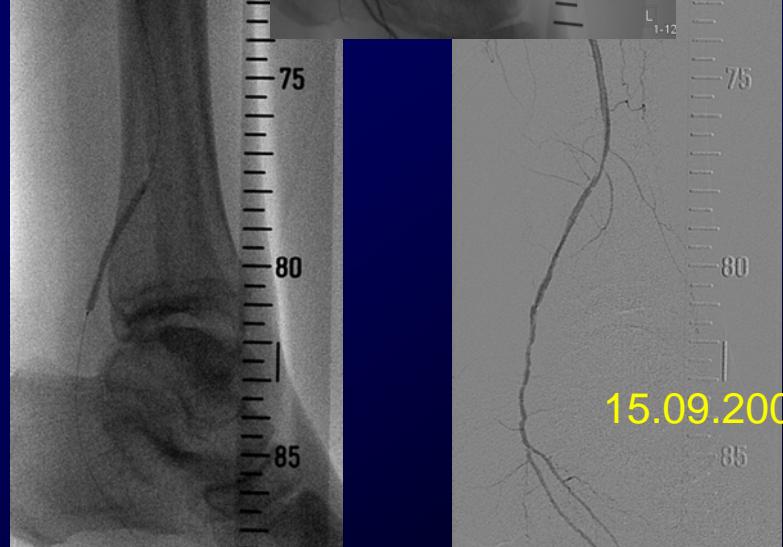


Dilatation 2/20 Balloon



06.03.2007

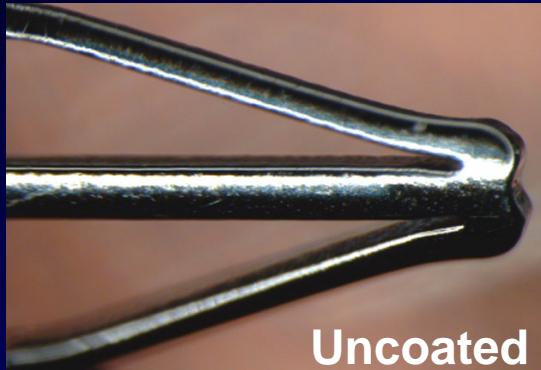
Re-Intervention



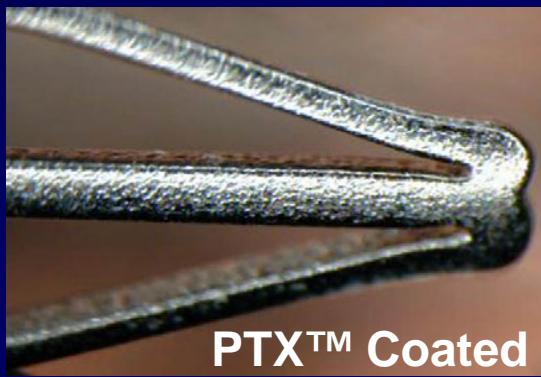
15.09.2009



Zilver® PTX™ Stent



Uncoated



PTX™ Coated

- Paclitaxel only
 - No polymer or binder
 - 3 µg/mm² dose density
- Zilver® Flex™
 - Self-expanding nitinol stent platform

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ilegx annual meeting
Oct 13-14 2009, Munich, Germany
under auspices of DGG (The German Vascular Society)

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INSTITUTE OF INTERVENTIONAL RADIOLGY
In association with the European Society of Radiology, the European Society of Vascular Surgery and the Society of Interventional Radiology

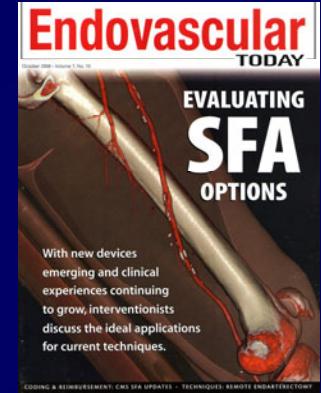
Interventional News - Latest News
Sethback for drug elution in the periphery as STRIDES follows SIROCCO
Fri 25-Sep-2009

Cook launch Europe's first drug-eluting stent for the SFA
Fri 25-Sep-2009

Interventional News - Features
UEMS Collection puts European IR in charge of its destiny
Thu 24-Sep-2009

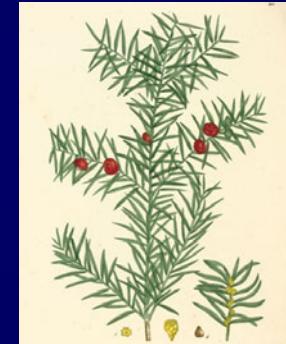
Opinote: A young interventional radiologist's perspective

CHARING CROSS
32nd Annual Conference
HOLD THE DATE
10-13 April 2010
Vascular & Endovascular Challenges update



Zilver® PTX™ Stent - Clinical Trial Indications

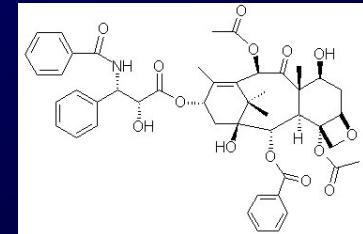
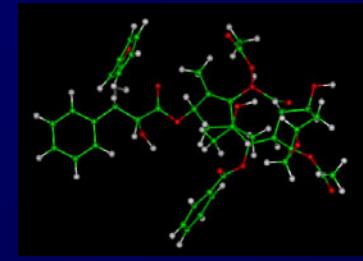
Paclitaxel (Taxol®) ist eine in der Pazifischen Eibe (*Taxus brevifolia*) vorkommende Substanz aus der Gruppe der Taxane



Taxane

- natürlich vorkommende Zytostatika
- chemische Gruppe Diterpenoiden (Diterpene)
- seit Anfang der 1990er Jahre in der Krebstherapie eingesetzt

- Paclitaxel wurde als erster Stoff aus der Gruppe der Taxane
 - erstmals 1983 einer klinischen Prüfung hinsichtlich seiner Einsetzbarkeit in der Krebstherapie beim Menschen unterzogen
 - 12 / 1993 erste Zulassung von Paclitaxel (Taxol®) in Deutschland zur Therapie des Ovarialkarzinoms



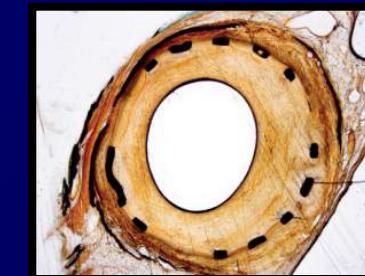
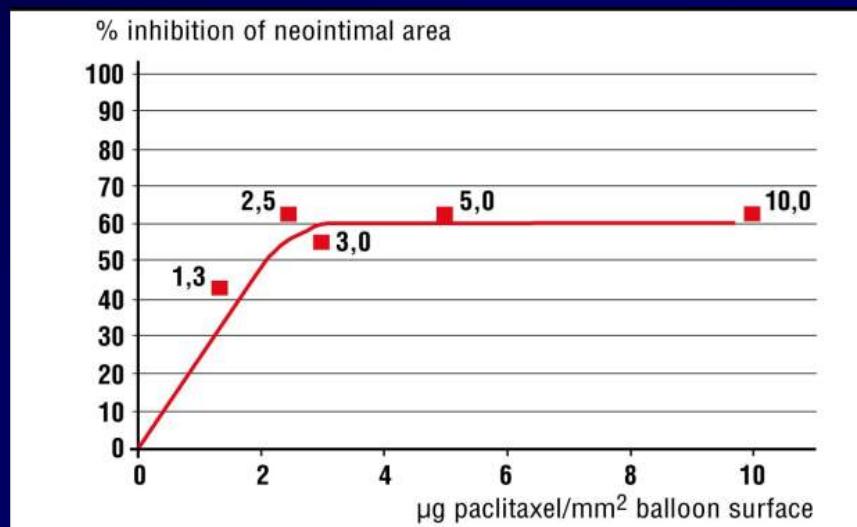
Zilver® PTX™ Stent - Clinical Trial Indications



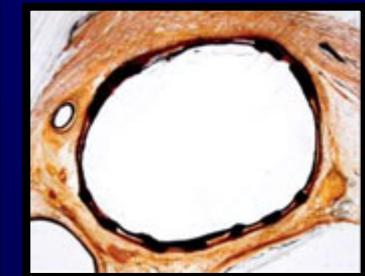
Paclitaxel (Taxol®)

Wirkungsmechanismus:

Paclitaxel - Bindung an Mikrotubuli - Inhibiert den Abbau der Mikrotubuli
Hemmung der Zellteilung



*Control (no drug):
thick
neointimal layer*



*FreePac™ coating
(3 $\mu\text{g paclitaxel}/\text{mm}^2$
balloon surface):
large open lumen*

Drug Eluting Stent

- langsame Freisetzung
- permanente Medikamentenabgabe
- Dosis ~ 100 – 200 μg

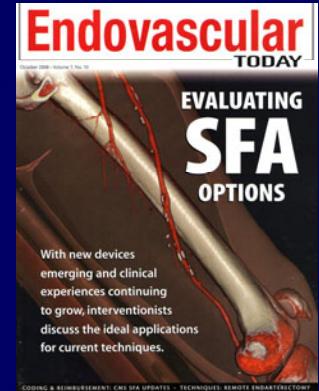
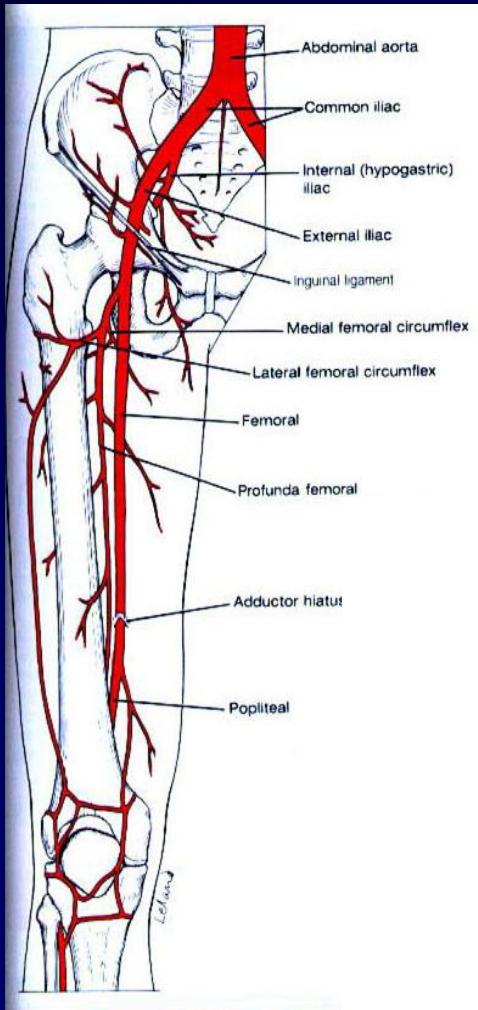


Zilver® PTX™ Stent - Clinical Trial

- Randomized Study (480 patients)
 - United States, Japan, and Germany
 - Patients treated with Bare Zilver stents or Zilver PTX stents
 - Enrollment complete
- Michael Dake, M.D. (Global Principal Investigator)
Professor of Cardiothoracic Surgery Stanford University School of Medicine
- Registry Study (791 patients)
 - Europe, Russia, Canada, and Korea
 - Patients treated with Zilver PTX stents
 - Enrollment complete
 - 12-month follow-up for 666 patients (760 lesions)
 - 24-month follow-up for 220 patients (266 lesions)



Zilver® PTX™ Stent - Clinical Trial Indications



- Treatment of symptomatic disease of the above-the-knee femoropopliteal artery
 - Proximal: 1 cm below bifurcation
 - Distal: medial femoral epicondyle
- Reference vessel diameter of 4 - 9 mm



Zilver® PTX™ Stent - Clinical Trial

Demographics

	12 Months	24 Months
Overall Patients (n)	666	220
Age (years)	67 ± 9	67 ± 9
Male	74%	77%
Height (cm)	170 ± 8	170 ± 8
Weight (kg)	79 ± 15	78 ± 15
Diabetes	35%	36%
High Cholesterol	59%	62%
Hypertension	81%	84%
Past/Current Smoker	80%	81%



Zilver® PTX™ Stent - Clinical Trial

Lesion Characteristics

	12 Months	24 Months
Patients	666	220
Lesions	759	266
TASC Class*:	A	27%
	B	29%
	C	26%
	D	14%
Lesion > 7 cm	47%	48%
Lesion > 15 cm	24%	27%
Total Occlusion	37%	36%
Restenosis (all)	24%	34%
In-stent Restenosis	15%	21%

*TASC 2000



Zilver® PTX™ Stent - Clinical Trial

Baseline Angiographic Data

	Overall Group (n = 774)	De novo (n=577)	Restenotic not ISR (n=79)	In-stent Restenosis (n = 116)
Lesion Length (cm)	9.9 ± 8.2	9.2 ± 7.8	10.4 ± 8.9	12.4 ± 8.6
Proximal RVD (mm)	5.4 ± 0.8	5.4 ± 0.9	5.3 ± 0.8	5.6 ± 0.7
Distal RVD (mm)	5.2 ± 0.8	5.3 ± 0.9	5.1 ± 0.8	5.3 ± 0.8
MLD in lesion (mm)	0.83 ± 0.88	0.85 ± 0.92	0.81 ± 0.83	0.72 ± 0.73
% Diameter Stenosis	84 ± 17	84 ± 18	85 ± 16	87 ± 14
Avg. Stents per Lesion	1.9	1.9	2.0	2.3

Lesions in all patients who reached 6-month follow-up



Zilver® PTX™ Stent

Möglichkeiten und Perspektiven...

Zilver® PTX™



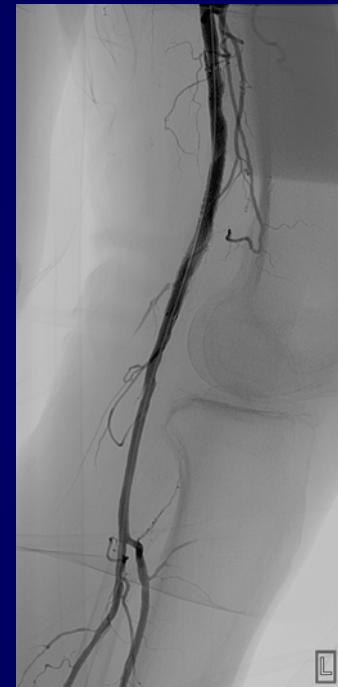
COOK MEDICAL Zilver® PTX®
DRUG-ELUTING PERIPHERAL STENT



Zilver® PTX™ Stent

Möglichkeiten und Perspektiven...

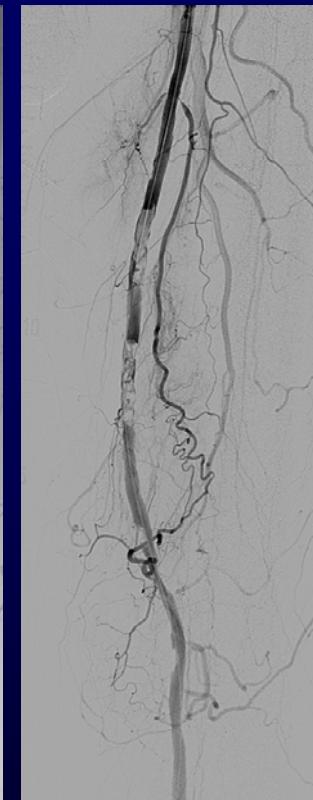
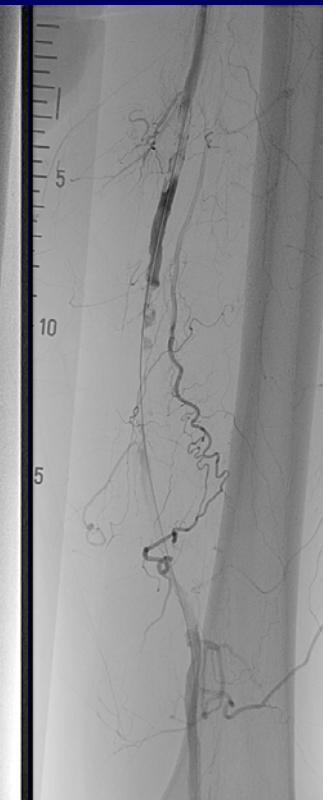
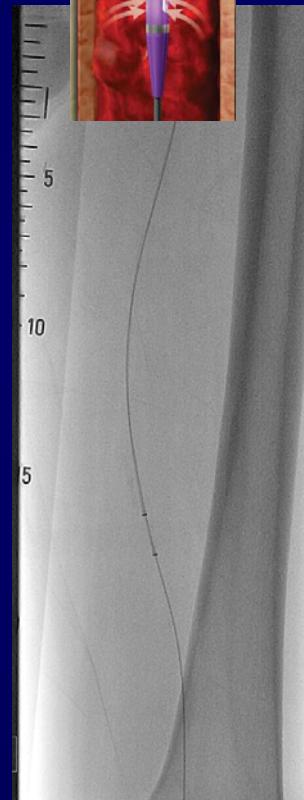
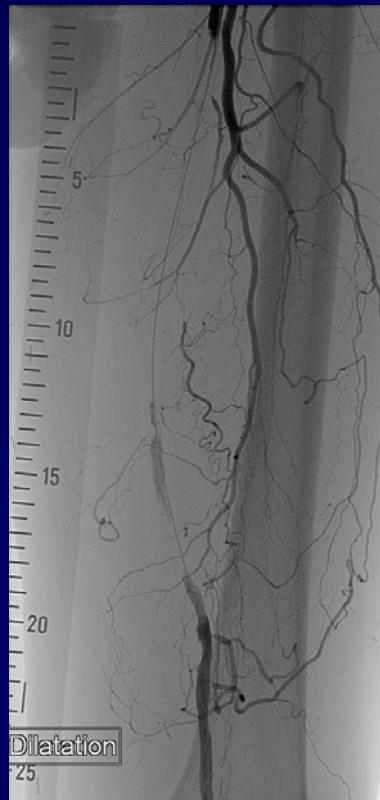
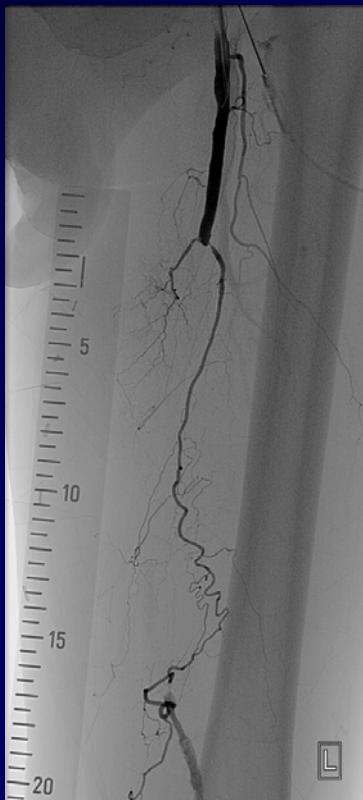
Zilver® PTX™





Zilver® PTX™ Stent

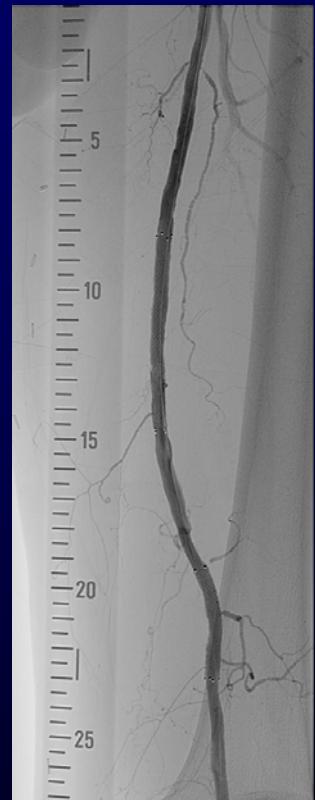
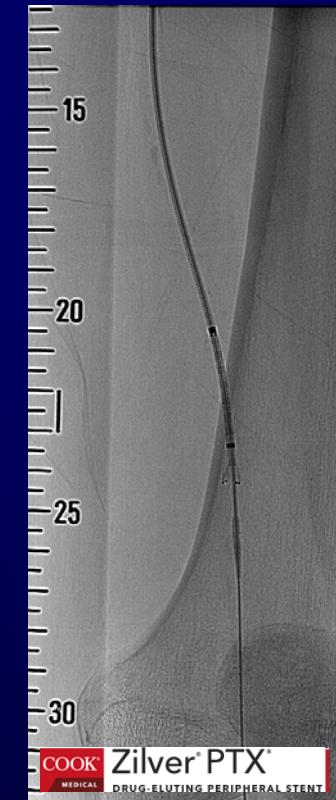
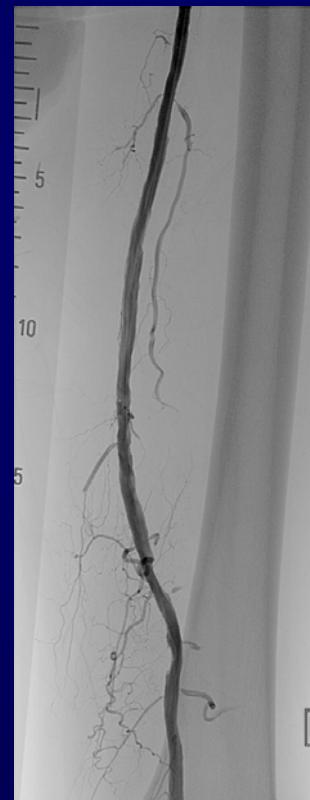
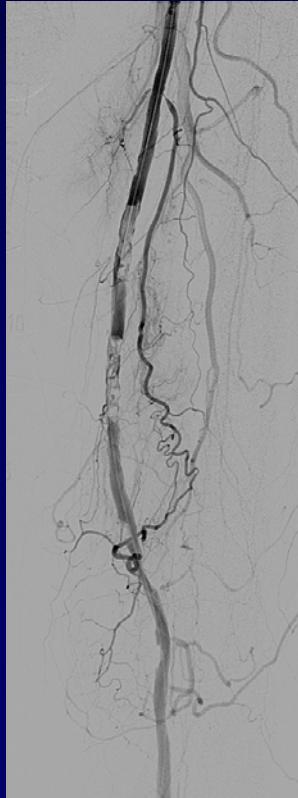
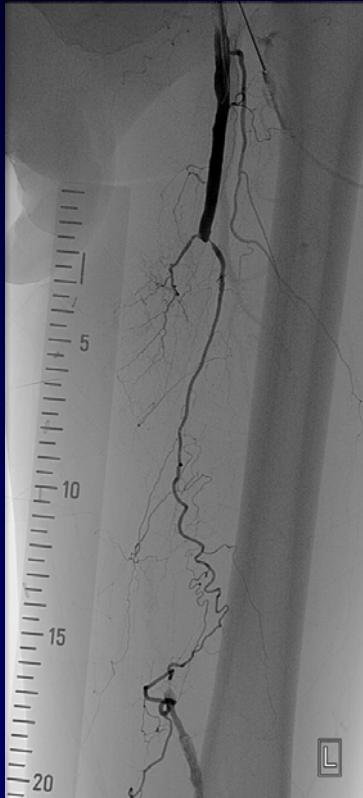
Möglichkeiten und Perspektiven... Angiojet





Zilver® PTX™ Stent

Möglichkeiten und Perspektiven... Zilver® PTX™





Zilver® PTX™ Stent - Clinical Trial

Results

	12 Months	24 Months
Stent Integrity: Potential Fractures	1.8% (24/1322 stents)	N/A
Safety: Event-free Survival	88% (587/671 patients)	78% (175/224 patients)

Event-free survival, defined as freedom from:

- Death
- Amputation
- Revascularization
- Significant worsening of Rutherford Classification



Zilver® PTX™ Stent - Clinical Trial Results

	12 Months	24 Months
Stent Integrity:	1.8%	N/A
Potential Fractures	(24/1322 stents)	
Safety: Event-free Survival	88% (587/671 patients)	78% (175/224 patients)
Effectiveness: Freedom from TLR	89% (677/760 lesions)	82% (218/266 lesions)

Target Lesion Revascularization (TLR), defined as:

- Clinically driven re-intervention for $\geq 50\%$ DS within treated segment (including ± 5 mm)
- Surgical bypass of target vessel



Zilver® PTX™ Stent - Clinical Trial

Results - Freedom from TLR

Subgroup	12 Months	24 Months
Overall	89% (n = 760)	82% (n = 266)
De novo (all)	92% (n = 574)	87% (n = 174)
< 7 cm Lesions	95% (n = 311)	90% (n = 90)
> 7 cm to 15 cm Lesions	93% (n = 143)	87% (n = 45)
> 15 cm Lesions	86% (n = 110)	81% (n = 36)
TASC C and D*	86% (n = 301)	73% (n = 111)
Occlusions	87% (n = 285)	77% (n = 95)
Stenosis	90% (n = 473)	85% (n = 171)
Restenosis (all)	82% (n = 183)	72% (n = 90)
Restenosis (not ISR)	86% (n = 70)	74% (n = 34)
In-stent Restenosis (ISR)	77% (n = 113)	71% (n = 56)

*TASC 2000



Zilver® PTX™ Stent - Clinical Trial

Results - Clinical Outcome

Clinical Measure	Pre-procedure	12 Months	24 Months
ABI	0.64 ± 0.26 (n = 696)	$0.90 \pm 0.24 *$ (n = 643)	$0.87 \pm 0.21 *$ (n = 214)
Most Common Rutherford Score	3 (n = 433/763)	0 * (n = 325/627)	0 * (n = 94/209)
Walking Distance Score	31 ± 26 (n = 669)	$72 \pm 32 *$ (n = 629)	$67 \pm 34 *$ (n = 199)
Walking Speed Score	35 ± 28 (n = 653)	$66 \pm 31 *$ (n = 615)	$65 \pm 31 *$ (n = 197)

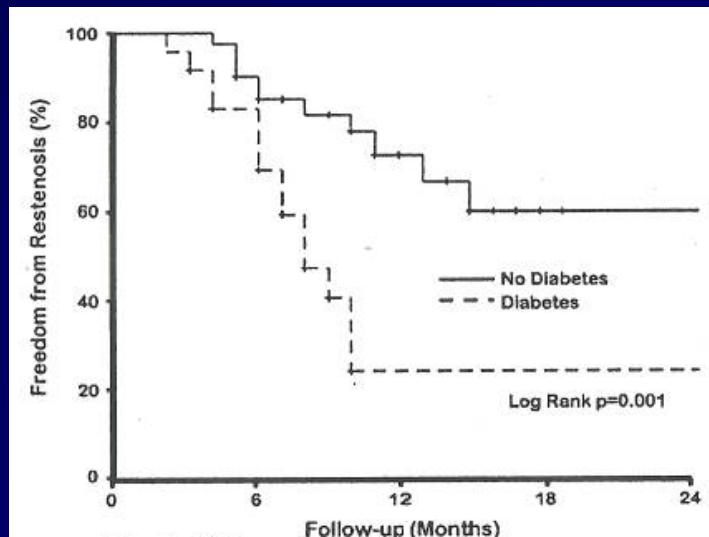
* $p < 0.01$ compared to pre-procedure



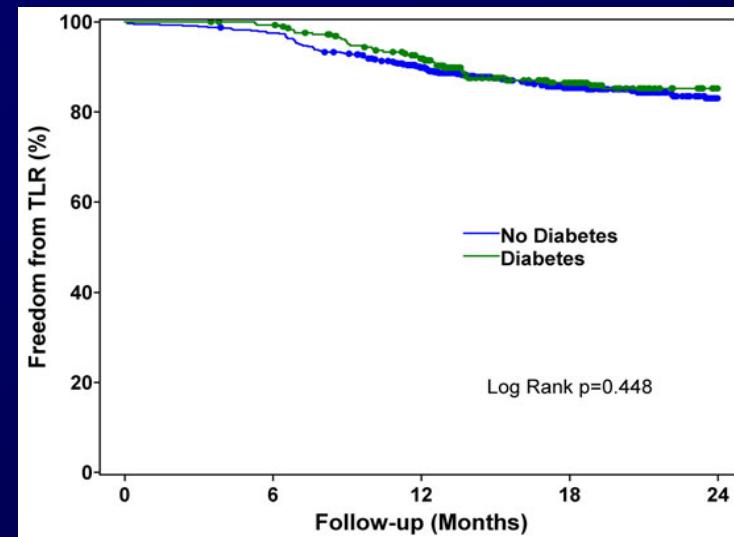
Zilver® PTX™ Stent - Clinical Trial

Results - Freedom from TLR

Subgroup	12 Months	24 Months
Overall	89% (n = 760)	82% (n = 266)
Not Diabetic	89% (n = 499)	80% (n = 172)
Diabetic	89% (n = 261)	86% (n = 94)



Self-Expanding Nitinol Stents
Sabeti, et al. J Endovasc Ther, 2550;12:6-12



Zilver® PTX™ Registry



Zilver® PTX™ Stent - Clinical Trial

Literature Comparisons: TLR at 12 and 24 Months

Literature		Matching Registry Subset	
Study	Inclusion Criteria	TLR	TLR
Resilient: (Katzen ISET 2008 and VEITH 2008)	<ul style="list-style-type: none">• No in-stent restenosis• Lesion length < 15 cm• Rutherford 1-3	LifeStent 13% at 12 months (n = 153)	Zilver® PTX™ 5% at 12 months (n = 442)
		20% at 24 months (n = 153)	Zilver® PTX™ 8% at 24 months (n = 143)
FAST: (Krankenberg 2007)	<ul style="list-style-type: none">• De novo lesions• Length 1 - 10 cm<ul style="list-style-type: none">- Multiple lesions < 10 cm total• ≥ 70% DS	Luminexx Stent 15% at 12 months (n = 127)	Zilver® PTX™ 5% at 12 months (n = 263)
Durability: (Scheinert TCT 2008)	<ul style="list-style-type: none">• No in-stent restenosis• Lesion length ≤ 14 cm• Rutherford 2-4	Protégé EverFlex Stent 21% at 12 months (n = 134)	Zilver® PTX™ 5% at 12 months (n = 446)



Conclusions

- The Zilver® Flex stent platform appears to have excellent durability (i.e., fracture resistance) in the SFA
 - 1.8% (24/1322 stents) fracture rate at 12-months
 - 1% (1/96 stents) fracture rate at 2.4 years for Zilver® Flex stent platform reported by Ferreira
- Outcomes through 2 years with the Zilver® PTX™ stent show
 - No safety concerns apparent
 - Favorable effectiveness (TLR rates, clinical outcomes, comparison to literature)



