

NOVA-X
THE ULTIMATE PROTECTION

**FINAL RESULTS
OF NOVARAD STUDY**

NOVARAD IS A MULTICENTRIC, TWO-ARM PROSPECTIVE STUDY, ASSESSING X-RAY DOSES REDUCTION USING NOVA-X®, A NEW FULL-BODY AND TEAM-WIDE RADIATION PROTECTION SYSTEM FOR CATH LAB STAFF DURING NEUROVASCULAR PROCEDURES.

STUDY DESIGN



3 OPERATORS AT THE SAME TIME
• 20 operator 1



DIFFERENT ANATOMIC POSITIONS
• 7 for operators 1 and 2
• 4 for operator 3



178 PROCEDURES IN 4 FRENCH CENTERS
• Bicêtre University Hospital
• Nantes University Hospital
• Toulouse University Hospital
• Besançon University Hospital



LAST-GENERATION OPERATIONAL DOSIMETERS
EPD Mk3, APVL, France
• Minimum detection level = 0.1 µSv (vs. 1.0 µSv for similar studies in interventional cardiology)
• Detection of minimal doses < 15 keV (vs. <30 keV for similar studies in interventional cardiology)

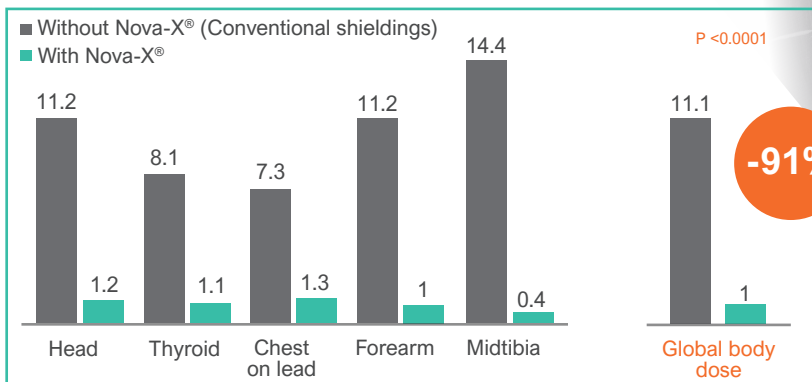
PROCEDURAL CHARACTERISTICS

Variable	CPE* - without Nova-X (n=90)	Nova-X (n=88)
Center ID		
01	28 (31.1%)	25 (28.4%)
02	25 (27.8%)	33 (37.5%)
03	10 (11.1%)	4 (4.5%)
04	27 (30.0%)	26 (29.5%)
Lead apron thickness		
0.5 mm	46 (51.0%)	39 (44.0%)
0.35 mm	39 (43.0%)	38 (43.0%)
0.25 mm	5 (6.0%)	11 (12.0%)
Type of artery access		
Femoral	76 (84.4%)	76 (86.4%)
Radial	7 (7.8%)	5 (5.7%)
Two access	7 (7.7%)	7 (7.9%)
Type of procedure		
Aneurysm	37 (41.1%)	41 (46.6%)
Arteriography	29 (32.2%)	27 (30.7%)
Embolization MAV/FAV	9 (10.0%)	6 (6.8%)
Thrombectomy	8 (8.9%)	4 (4.5%)
Embolization SDH	2 (2.2%)	4 (4.5%)
Venous stending	2 (2.2%)	3 (3.4%)
Angioplasty	2 (2.2%)	1 (1.1%)
Spinal arteriography	0 (0.0%)	1 (1.1%)
Other	1 (1.1%)	1 (1.1%)
Intervention duration (min)		
Mean	85.91	86.60
Median	74.00	74.00
Min-Max	13.00 - 280.00	14.00 - 276.00
Dose Area Product (Gy.cm²)		
Mean	104.06	83.47 P. value <0.001
Median	86.00	64.35
Min-Max	10.70 - 480.00	5.13 - 295.00

*CPE: Conventional Protective Equipment

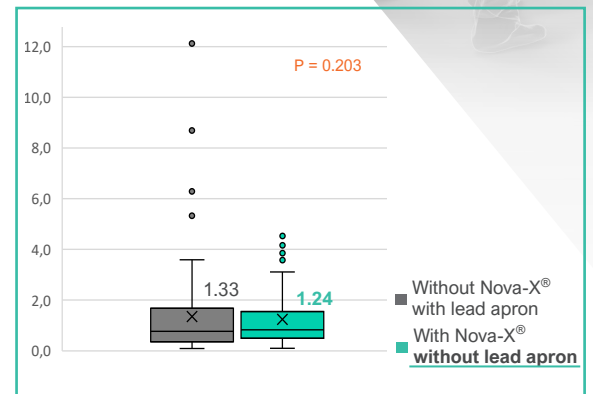
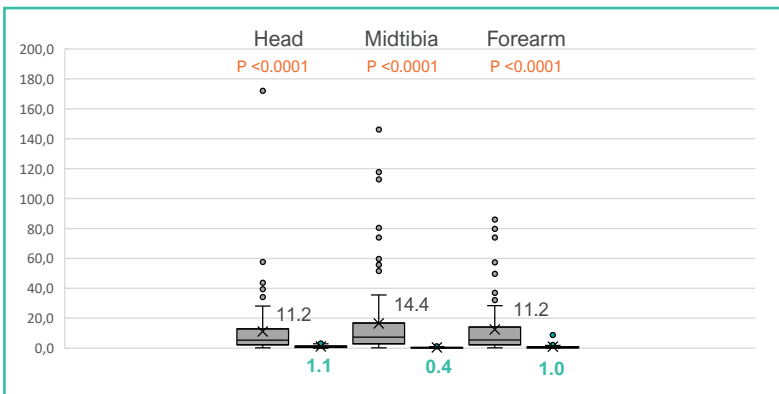
DOSES PER PROCEDURE PER OPERATOR (in μSv) ALL CENTERS

OPERATOR 1 MEAN DOSE PER PROCEDURE BY ANOMIC POSITION (in μSv)

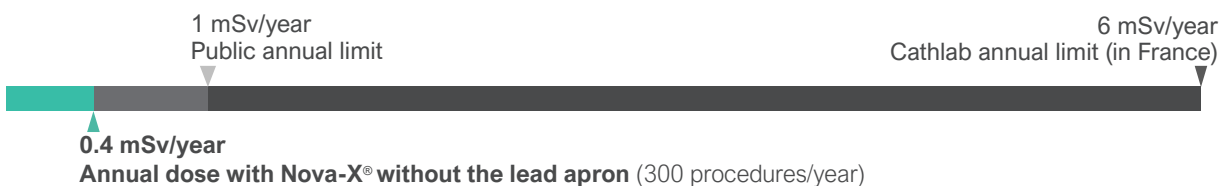


LEAD-FREE PROCEDURES

DETERMINISTIC AND STOCHASTIC RISK EVALUATION (in μSv)



EFFECTIVE DOSE PER YEAR FOR 300 PROCEDURES (in mSv/year)



NOVARAD CONCLUSION

Nova-X[®] prevents from all types of risks (deterministic, stochastic and MSD) opening the possibility to work safely without wearing the lead apron

- Operator 1 mean dose per procedure is divided by:
 - 11 globally (1.0 μSv with Nova-X[®] vs 11.1 μSv with CPE, p-value < 0.001)
 - 11 at the head and forearm (1.2 μSv and 1.0 respectively with Nova-X[®] vs 11.2 and 11.2 μSv with CPE, p-value < 0.001)
 - 36 at the midtibia (0.4 μSv with Nova-X[®] vs 14.4 μSv with CPE, p-value < 0.001)
- Operator 1 effective dose is similar in both groups: Nova-X[®] without the lead (1.2 μSv) and conventional shieldings (1.3 μSv)
- Operators 2 and 3 global body dose is divided by 6 and 3 respectively with mean doses using Nova-X[®] of 1 μSv per procedure and 0.4 μSv

Nova-X[®] is a Class I medical device.
The Nova-X[®] consumable kit is a Class Is medical device.
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