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Appendix

Supplemental Methods:

System Sterile Processing and Logistics

GENERAL STATEMENT of PURPOSE
The purpose of this document is to ensure consistency in the performance and safe operation of Immediate Use Steam Sterilization (IUSS).
POLICY
It is the policy of Northwell Health that Immediate Use Steam Sterilization (IUSS) must be kept to a minimum; used only in an emergent procedure and when authorized by a nominated member of the management team.
SCOPE
This policy applies to all Northwell Health employees, as well as medical staff, volunteers, students, trainees, physician office staff, contractors, trustees and other persons performing work for or at Northwell Health; faculty and students of the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell or the Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies conducting research on behalf of the Zucker School of Medicine on or at any Northwell Health facility.

DEFINITIONS
Emergent Procedure- "Emergent" is defined as a clinical situation in which any delay incurred places the patient at risk of imminent harm to life, or serious threat to health.
Immediate Use Steam Sterilization (IUSS) - Describes sterilization of unwrapped devices for immediate use (not intended to be stored for later use). "Immediate use" is broadly defined as the shorted possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants.
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PROCEDURE
1. All Immediate Use Steam Sterilization require approval from Perioperative Leadership Team and/or designee.
2. Manufacturer's instructions for any device must support the use of IUSS.
3. If an item falls on the floor intra-operatively, every effort must be made to obtain a sterile alternative device.
4. If a sterile replacement is unavailable, then the contaminated instrument must be decontaminated in the sub-utility room with an enzymatic detergent according to Policy #SSPLl.2.1732, *Safe Handling and Decontamination of Soiled Instrumentation*.

5. Select the appropriate cycle for the device being sterilized, either 4 minutes at 270°F/132°C for all non-porous, non-lumen items, or 10 minutes at 270°F/132°C for all items with a lumen, porous, or any item in an immediate use steam sterilization pack (always consult the manufacturer's instructions).
6. If the sterilizer is not located adjacent to the OR the item must be placed in an immediate use steam sterilization pack for transportation and sterilized for 10 minutes. Before use confirm the daily BI test has been carried out on the sterilizer used and a satisfactory result obtained.
7. A class 5 or 6 chemical integrator must be used within each sterilization container or tray used for IUSS.

NOTE: Only authorized trained and competent personnel will operate IUSS processes and verify that all parameters have been met at the completion of the sterilization cycle and be responsible for completion of the appropriate documentation. These tasks will be performed by a suitably trained and competent individual.
8. IUSS items MUST be used immediately and not stored for later use.
9. The "**Immediate Use Steam Sterilization Log**" must be completed with the following information: a) Date & Time
b) Sterilizer Number
c) Item Sterilized
d) Reason for using IUSS
e) Patient Identification Sticker
f) Signature of person verifying cycle
g) Operating Surgeon Emergent Procedure Attestation

NOTE: These logs will be collected, reviewed, and maintained for 7 years
Refer to policy #100.97 Records, Retention and Destruction
IUSS MUST NOT BE PERFORMED ON THE FOLLOWING DEVICES:
a) Implants or surgical instruments, except in a documented emergency situation when no other option is available and written authorization from the surgeon.
b) Post-procedure decontamination of instruments used on patients classified as "high risk" of having Creutzfeldt-Jakob disease (CJD) or similar disorders.

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c) Devices or loads that have not been validated to the IUSS cycles available.
d) Devices that are sold sterile and intended for single-use only.

CLINICAL REFERENCES/PROFESSIONAL SOCIETY GUIDELINES
AORN Perioperative Standards 2014, Recommended Practice: Sterilization Recommendation IV pg 581-582
REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES
IAHCSMM 7th Edition, 2016
AAMI Guidelines (2013), ST: 79; Section 8: Sterilization for Immediate Use, 8.6.2-8.6.2.5

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#100.97 Records, Retention and Destruction

Supplemental Table 1: Reason for IUSS by SSI

	SSI		
Reason for IUSS	**No**	**Yes**	**Total***
Bioburden	121 97·58%	3 2·42%	124
Damaged Item	8 100%	0 0%	8
Failed Indicator	11 91·67%	1 8·33%	12
Hole in Wrap or Filter	1,098 98·74%	14 1·26%	1,112
Incorrect Label	22 100%	0 0%	22
Item Dropped	294 99·32%	2 0·68%	296
Item Missing From Tray	210 99·06%	2 0·94%	212
Late Tray	156 96·30%	6 3·70%	162
MD's Instrument	83 97·65%	2 2·35%	85
Manufacturer Guideline	1 100%	0 0%	1
Missing Indicator/Filter	89 96·74%	3 3·26%	92
Other	70 100%	0 0%	70
Re-Use	1,045 97·75%	24 2·25%	1,069
Wet Pack/Tray	208 98·58%	3 1·42%	211
Wrong Item in Tray	14 93·33%	1 6·67%	15
Total	3,430	61	3,491

**Frequency Missing (N = 35)*

Abbreviations: immediate-use steam sterilization (IUSS), surgical site infection (SSI).

Supplemental Table 2: Comparability of the groups before and after PSM by IUSS status

Variable		IUSS	non-IUSS	Mean Difference	Standardized Difference
Age (years)	Before PSM	61·53	63·41	-1·87917	-0·12750*
	Matched	61·53	61·14	0·39223	0·02661
Procedure Time (min)	Before PSM	159·05	128·2	30·8506	0·36965*
	Matched	159·05	160·63	-1·57402	-0·01886
BMI (kg/m^2)	Before PSM	30·3	30·06	0·2458	0·03639
	Matched	30·3	30·28	0·02985	0·00442
Diabetes	Before PSM	0·148	0·1665	-0·01849	-0·0508
	Matched	0·148	0·1529	-0·00482	-0·01325
Gender	Before PSM	0·4498	0·4235	0·02627	0·05298
	Matched	0·4498	0·4504	-0·00057	-0·00114
HPRO	Before PSM	0·2365	0·2976	-0·0611	-0·13842*
	Matched	0·2365	0·2289	0·00766	0·01735
FUSN	Before PSM	0·3902	0·2271	0·16312	0·35872*
	Matched	0·3902	0·4104	-0·02014	-0·04428
LAM	Before PSM	0·0848	0·0868	-0·00202	-0·0072
	Matched	0·0848	0·0754	0·00936	0·03341
Hospital Site # 1	Before PSM	0·0017	0·0306	-0·02891	-0·23081*
	Matched	0·0017	0·0023	-0·00057	-0·00453
Hospital Site # 2	Before PSM	0·0043	0·0038	0·00048	0·00763
	Matched	0·0043	0·0037	0·00057	0·00897
Hospital Site # 3	Before PSM	0·0908	0·0771	0·01369	0·04939
	Matched	0·0908	0·0859	0·00482	0·01739
Hospital Site # 4	Before PSM	0·04	0·106	-0·06606	-0·25597*
	Matched	0·04	0·0397	0·00028	0·0011
Hospital Site # 5	Before PSM	0·042	0·0974	-0·05544	-0·21902*
	Matched	0·042	0·0431	-0·00113	-0·00448
Hospital Site # 6	Before PSM	0·4399	0·1489	0·29097	0·67358*
	Matched	0·4399	0·4368	0·00312	0·00722
Hospital Site # 7	Before PSM	0·0241	0·0353	-0·01123	-0·06615
	Matched	0·0241	0·0261	-0·00199	-0·0117
Hospital Site # 8	Before PSM	0·0034	0·0672	-0·06376	-0·35087*
	Matched	0·0034	0·0028	0·00057	0·00312

Hospital Site # 9	Before PSM	0·1086	0·0966	0·01198	0·03949
	Matched	0·1086	0·1021	0·00652	0·0215
Hospital Site # 10	Before PSM	0·0559	0·1249	-0·06905	-0·24256*
	Matched	0·559	0·604	-0·00454	-0·01594
ASA Class 2	Before PSM	0·4685	0·4904	-0·02183	-0·04371
	Matched	0·4685	0·4575	0·01106	0·02214
ASA Class 3	Before PSM	0·4742	0·4552	0·01898	0·03806
	Matched	0·4742	0·4824	-0·00822	-0·01649
ASA Class 4	Before PSM	0·0335	0·0226	0·01085	0·06574
	Matched	0·0335	0·0346	-0·00113	-0·00687
ASA Class 5	Before PSM	0·0006	0·0004	0·00019	0·00897
	Matched	0·06	0·09	-0·00028	-0·01308
Wound Class	Before PSM	0·9824	0·9921	-0·00971	-0·08671
	Matched	0·9824	0·9861	-0·00369	-0·03292
Emergency Procedure	Before PSM	0·0493	0·0347	0·01462	0·07292
	Matched	0·0493	0·0442	0·0051	0·02545
Endoscopic Procedure	Before PSM	0·0099	0·0066	0·00332	0·03669
	Matched	0·0099	0·0096	0·00028	0·00313
Trauma	Before PSM	0·0374	0·0365	0·00094	0·00498
	Matched	0·0374	0·0352	0·00227	0·01202
Closure	Before PSM	0·9994	0·9985	0·00089	0·02808
	Matched	0·9994	0·9994	0	0

Standard deviation of all observations used to compute standardized differences

Abbreviations: immediate-use steam sterilization (IUSS), American Society of Anesthesiologists (ASA), knee prosthesis (KPRO), hip prosthesis (HPRO), laminectomy (LAM), fusion (FUSN), propensity score matching (PSM), clean (C), clean-contaminated (CC), contaminated (CO), dirty (D).

*: Indicates significant difference before PSM as compared to after PSM.

Supplemental Table 3: Table of Implant IUSS by SSI

	SSI		
IUSS of Implant	**No**	**Yes**	**Total***
No	3,138 98·22%	57 1·78%	3,195
Yes	199 98·51%	3 1·49%	202
Total	3,337	60	3,397

**Frequency Missing (N = 129)*

Abbreviations: immediate-use steam sterilization (IUSS), surgical site infection (SSI).

Supplemental Table 4: Table of Number of Items Sterilized Using IUSS by SSI

	SSI		
	No	**Yes**	**Total***
Full Tray	2,219 98·19 %	41 1·81%	2,260
Multiple Items	317 97·54 %	8 2·46%	325
Single Items	928 98·72 %	12 1·28%	940
Total	3,464	61	3,525

**Frequency Missing (N = 1)*

Abbreviations: surgical site infection (SSI), immediate-use steam sterilization (IUSS).

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Supplemental Table 5: Table of Indicator Tape by SSI

	SSI		
	No	**Yes**	**Total***
Negative	3,023 98·3%	54 1·75%	3,077
Positive	438 98·4%	7 1·57%	445
Total	3461	61	3,522

**Frequency Missing (N = 4)*

Abbreviations: surgical site infection (SSI)