

Catalog number(s): This Post Sterilization Specification (PSS) is applicable to:

- Sterile Catalog Items produced by Busse Hospital Disposables
- EtO Processed Laminaria

Inspection Instructions: Verify that returned case count matches quantity produced and quantity sent to contract sterilizer. Quantity discrepancies must be resolved prior to release.

Document quantity of cases repacked/scrapped.

The number of units in the sample that are defective shall be tallied by class (*Critical*, *Major*, and *Minor*). If this tally is equal to or less than the Accept Number for defectives, the lot is accepted, otherwise the tally will be greater than the Accept Number and the lot is to be rejected.

Sample as follows:

SHIPPING CARTONS: Damage Only n= 100% of cases.

Other Defects n= square root +1 of the total number of shipping containers.

DISPENSER CARTONS: n= 100% of dispenser cartons from the square root + 1 of the total number of shipping cartons.

UNITS: n=80 units

Draw samples from the square root +1 of the total number of cases and inspect for the following:
Record results on Inspection Data Sheet (IDS) Attachment I.

	<u>DEFECT</u>	<u>CLASS</u>	<u>ACCEPT NUMBER</u>
LABELING:	1 - Incorrect/Missing/Illegible Lot Number on Unit Package	Critical	0
	2 - Incorrect/Missing/Illegible Catalog Number on Unit Package	Critical	0
	3 - Incorrect/Missing/Illegible Expiration Date* on Unit Package	Critical	0
	4 - Incorrect / Missing Content Card*	Critical	0
	5 - Incorrect/Missing/Illegible Lot Number on Dispenser Carton	Critical	0
	6 - Incorrect/Missing/Illegible Catalog Number on Dispenser Carton	Critical	0
	7 - Incorrect/Missing/Illegible Expiration Date* on Dispenser Carton	Critical	0
	8 - Incorrect/Missing/Illegible Lot Number on Shipping Carton	Critical	0
	9 - Incorrect/Missing/Illegible Catalog Number on Shipping Carton	Critical	0
	10 -Incorrect/Missing/Illegible Expiration Date* on Shipping Carton	Critical	0

** If applicable to product.*


	<u>DEFECT</u>	<u>CLASS</u>	<u>ACCEPT NUMBER</u>
PACKAGE INTEGRITY:	11 -Separated / Open seals	Critical	0
	12 -Channels / Bulges in seal	Critical	0
	13 -Damaged Dispenser Cartons or Shipper cartons (Ripped, punctured, crushed, wet)	Critical	0
	14 – Incorrect Component/Dispenser Carton/Shipper Carton used*	Critical	0
	15 – Damaged package (Rips, tears, punctures)	Major	3
	16 – Component caught in seal	Major	3
PACKAGE CONTENTS:	17 – Missing / Incomplete Component	Critical	1
	18 – Empty packages	Critical	1
	19 – Leaking rust colored residue from instruments*	Minor	10
	20 – Leaking Component (Saline or Wet Pack) *	Major	3
	21 – Obvious embedded or loose debris in package	Major	3
	22 – Product discoloration	Major	3
MISC:	23 – Minor loose or embedded debris in package	Minor	4
	24 – Miscellaneous Critical Defect	Critical	1
	25 – Miscellaneous Major Defect	Major	3
	26 – Miscellaneous Minor Defect	Minor	4

** If applicable to product.*

Original signatures appear on referenced DCO.

Packaging Manager
Manufacturing Manager
Quality Manager
Quality Lead Inspector
Quality Technician

ATTACHMENT I

		INSPECTION DATA SHEET	
DATE:	_____	QUALITY INSPECTOR:	_____
CATALOG NUMBER	_____	LOT NUMBER:	_____
DESCRIPTION:	_____	PO NUMBER:	_____
QUANTITY VERIFICATION			
Qty Produced:	_____	Qty Sent to Sterilizer:	_____
		Qty Received:	_____
		Difference:	_____
CASE DAMAGE			
Qty Repacked:	_____	Qty Scrapped:	_____
INSPECTION RESULTS			
SHIPPER CARTON n= _____	Damaged	Qty	Defect Description
n= _____	Other	_____	_____
		_____	_____
		_____	_____
DISPENSER CARTON: n= _____		Qty	Defect Description
		_____	_____
		_____	_____
		_____	_____
UNIT: n=80 units		Qty	Defect Description
		_____	_____
Defect Totals			
Critical	_____	_____	_____
Major	_____	_____	_____
Minor	_____	_____	_____
QTY ACCEPTED:	_____	QTY REJECTED:	_____
		QTY SCRAPPED:	_____
COMMENTS:	_____		

DCO #	Form # 100-01		