## SHARPS CONTAINER GUIDE

FOR THE USA

Prepared in consultation with healthcare compliance and sharps regulatory experts



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Daniels examined U.S. regulations and guides for sharps containers and asked Users what else they required – the list is 139 items for disposable containers and 170 for reusable containers.

Sharps containers are governed by FDA, DOT and OSHA laws, have a U.S. Standard, a comprehensive NIOSH Selection Guide, and Users can list additional needs.

### **FDA Regulations & Guides**

FDA REGULATIONS & GUIDES 1.2.3.4	DISPOSABLE	REUSABLE
	[TICK FOR YES]	[TICK FOR YES]
All sharps containers <sup>1,2,3</sup>		
Have FDA 510(k) Market Clearance for product		
Company registered and products listed with FDA		
Compliant with CFR 21 Part 820 Quality System Regulation and Good Manufacturing Practices.		
Labeled with adequate directions for safe use		
OSHA compliant (Closable, Puncture resistant. Label/color-coded, Leak resistant on sides and bottom)		
Complies with a relevant sharps container standard for:		
Impact Resistance		
Puncture Resistance		
Overfill Detection		
Leak resistance		
Sharps Access and Closure		
- Stability		
Mounting Accessories		
Handling (safe transportation features)		   
Capacity		     

#### **Reusable Sharps Containers**<sup>4</sup>

Sharps container standard's performance tests are conducted after containers are subjected to:

	ated filling and emptying container of sharp an-uses, using normal processing	s, equal to stated		
• DOT	/ibration test			
Mana	s FDA cleaning-before-reuse requirements r gement, Design, Corrective & Preventive Ac rocess (21 CFR 820.20, .30, .70, .100)			
	F	DA SCORE	MAX 14	MAX 17

### **DOT Regulations. CFR 495**

DOT REGULATIONS <sup>5</sup>	DISPOSABLE	REUSABLE
All sharps containers		
173.134 - securely closable to prevent leaks or punctures		
173.197 - Must be puncture resistant		
178.134 - marked with a BIOHAZARD marking conforming to 29 CFR 1910.1030(g)(1)(i)		
171.8 & 172.101 - Labelled with proper UN Shipping Name & Number: UN 3291		
Sharps containers may be transported by private or contract carrier as Regulated Medical Waste in wheeled racks when containers are:		
<ul> <li>rigid non-bulk packaging conforming to the general packaging requirements of §§173.24 and 173.24a and packaging requirements specified in 29 CFR 1910.1030</li> </ul>	T	
<ul> <li>transported by a private or contract carrier in a vehicle used exclusively to transport regulated medical waste</li> </ul>		
securely closed to prevent leaks or punctures		
containers do not exceed 18 gallons capacity		
registered under the Medical Device Regulations of FDA		
made of puncture resistant plastic that meets ASTM Standard F2132-01		
<ul> <li>securely fitted into wheeled racks that hold them in an upright position; and racks are securely held in place on the motor vehicle</li> </ul>	T	
Sharps Containers passing DOT UN Packaging II Tests – CFR49-178.600 (For all sharps containers over 20 galls or certified to Packaging Group II)		
<ul> <li>178.503 - must mark every packaging that is represented as manufactured to meet a UN standard with the UN marks specified.</li> </ul>		
• 178.603 - Drop test (1.2m/4ft, -18C/0F)		
178-606 - Stacking Strength & stability Test		
178.608 - Vibration test (1 hour)		
Reusable Sharps Containers - 173.197		

# Must have a capacity between 2-40 galls (7.57-151.42 L) in vol. Permanently marked for reuse Approved & certified by U.S. FDA as a medical device for reuse Disinfected prior to reuse, effective for infectious substance previously contained

**MAX 15** 

**MAX 19** 

### OSHA Regulations. CFR 29-1910.10306

OSHA REGULATIONS <sup>®</sup>	DISPOSABLE	REUSABLE
All sharps containers		
(c)(1) – Employer shall:		
<ul> <li>Be reviewed annually review Exposure Control Plan to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens</li> </ul>	· <b>· · · · · · · · · · · · · · · · ·</b> ·	
<ul> <li>Document annually consideration and implementation of appropriate commercially available and effective safer medical devices</li> </ul>	·	+
<ul> <li>Solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation, and selection of effective engineering &amp; work practice controls</li> </ul>		
Document the solicitation in the Exposure Control Plan		
(d)(2)(i) - Engineering and work practice controls shall be used to eliminate or minimize employee exposure		
(d)(2)(ii) - Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness		
(d)(4)(iii)(A)(i) - Containers shall be:		
Closable		
• Puncture resistant		
Leakproof on sides and bottom		
Labeled/color-coded in accordance with (the standard)		
(d)(4)(iii)(A)(ii) - During use, containers shall be:		
<ul> <li>Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries)</li> </ul>	a	
Maintained upright throughout use		
Replaced routinely and not allowed to overfill		
Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping	F	
Placed in a secondary container if leakage is possible		
Needle unwinders. The use of these are generally prohibited 7		
<ul> <li>Needles shall not penetrate sharps containers.</li> <li>"If the container is considered puncture resistant by the manufacturer, but there is evidence, through observation or employee statements, that sharps have been protruding through a container, paragraph</li> </ul>		

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### **OSHA Regulations Continued...**

OSHA REGULATIONS	DISPOSABLE	REUSABLE
Reusable sharps containers		
• Shallbe inspected and decontaminated on a regularly scheduled basis. (d)(4)(ii)(C)		
<ul> <li>Shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury (d)(4)(iii)(A)(4)</li> </ul>		
<ul> <li>Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. (d)(2)(ii)</li> </ul>		
OSHA SCORE	MAX 17	MAX 20

### ASTM Standard. F2132-01 (2008)e18

ASTM STANDARD *	DISPOSABLE	REUSABLE
Sharps containers		
All areas of differing thickness/material on sharps container (including base, sides, closure, top) meet Penetration Test		
ASTM SCORE		
	MAX 1	MAX 1

### **NIOSH** Guideline for Sharps Containers

#### **NB. NIOSH score modified to match Checklist**

NIOSH GUIDELINE FOR SHARPS CONTAINERS <sup>®</sup>	DISPOSABLE	REUSABLE
All sharps containers		
Functionality		
Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures		
Container provides for puncture, leak, and impact resistance		
Container, labels, warning devices, and brackets are durable		
Container is autoclavable, if necessary		
Container is available in various sizes and capacities		
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required		
Closure mechanism will not allow needlestick injury		
Closure mechanism provides secure seal		
Design minimizes needle-tip flipback		
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)		
Design resists easy reopening after sealing for final disposal		
Inlet design defeats waste removal when open		
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position		
Containers designed to be reopenable have removable lids with tight closure facilitating ease of removal with grip safety & comfort		
Mounting brackets are rugged and designed for ease of service and decontamination		
Visibility		
Color or warning label implies danger.		
A warning indicator (i.e., color or warning label) is readily visible to the user prior to user placing sharps into container		
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container		
Sharps disposal container complies with OSHA requirements		
Disposal opening/access way is visible prior to user placing sharps into container		
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/ access way or fill status indicator		

### **NIOSH Guideline Continued...**

NIOSH GUIDELINE FOR SHARPS CONTAINERS	DISPOSABLE	REUSABLE
All sharps containers		
Accessibility	· · · · · · · · · · · · · · · · · · ·	
Container available in various opening sizes and shapes		
Containers are supplied in sufficient quantity		
Container has an entanglement-free opening/access way		
Container opening/access way and current fill status visible to user prior to placing sharps into container		
Internal design/molding of container does not impede ease of use		
Handles, if present, located above full-fill level		
Handles, if present, facilitate safe vertical transport and are located away from opening/ access way and potentially soiled surfaces		
Fixed locations place container within arm's reach of point of waste generation		
Fixed locations allow for installation of the container below horizontal vision level		
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering		
Accommodation		
No sharp edges in construction or materials		
Safety features do not impede free access		
Promotes patient and user satisfaction (i.e. aesthetic to extent possible)		
Components of containers that require assembly are easy to store prior to use		<b>F</b>     
Use allows one-handed disposal		
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)		
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable		
Mounting systems allow height adjustments		
Design promotes task confidence		
Cost effectiveness		

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### **NIOSH Guideline Continued...**

NIOSH GUIDELINE FOR SHARPS CONTAINERS	DISPOSABLE	REUSABLE
All sharps containers		
Additional NIOSH Requirements for Sharps Containers		
Remain functional during entire usage until final disposal		
Inlet prevents spillages during closure, sealing & transport in facility		
Durability and puncture resistance unaffected by minor changes in temperature during storage and use.		
Materials resistant to chemical or liquid permeation or degradation, tearing, abrasion and laceration		
Available in size able to accommodate largest sharps		
Has mechanism to restrict hand-entry during use, including children's hands.		
Handles are sturdy		
Designed for simple, easy and safe disposal of sharps		
Available with mountings on wheels.		
Design should minimize cross infection hazards		
Easy, safe placement and removal from mounting systems		
Mountings designed specifically for system		
Worker training provided before system introduced		
Multilingual educational materials, where appropriate		
Sufficient quantities of containers available for projected volumes		

### **NIOSH Guideline Continued...**

NIOSH GUIDELINE FOR SHARPS CONTAINERS	DISPOSABLE	REUSABLE
User Instructions Include		
All sharps containers		
Assembly (where appropriate)		
Safety considerations		
Optimal storage conditions		
Warranty information		
Bilingual or multilingual material, where needed		     
Information for periodic in-service re-training, if required		
Reusable sharps containers		
Maintenance criteria available		
Mountings designed specifically for system		
Worker training provided before system introduced		
NIOSH SCORE		
	MAX 64	MAX 67

### **Additional Requirements by Users**

#### (HCW focus group workshops)

ADDITIONAL REQUIREMENTS BY USERS	DISPOSABLE	REUSABLE
All sharps containers		
Peer-reviewed published studies confirm system's ability to reduce sharps injuries		
Written evaluations confirm high approval rating by clinical users		
Certified leakproof when dropped on lid		
Color-coded containers for Pharmaceutical sharps waste		
Stable when used or stored (i.e. pass 150 Topple Test)		
Preassembled		
Intuitive and simple to use		
Foot-operated models available		
Patient-room containers have large opening with passive safety features allowing safe sharps disposal but restrict hand entry.		
Needle unwinder absent		
Container promotes wall-space efficiency (no cabinet)		
Passive safety features prevent overfilling and protrusion injuries		
Bracketry enables ergonomic container placement at all workstations, including walls, benches, carts, gurneys		
Universal bracketry enables different container sizes to be interchanged without changing bracketry		
Have both temporary and permanent closures		
Temporary closure device enables safe closure and movement		
Tamper-proof when permanently closed for disposal		
Closure mechanisms are integrally attached to container		
Designed to facilitate vertical stacking		
Safe, ergonomic & spatially-economic on-site storage systems		
Multi-media education systems for users		
Electronic summary of container locations available		

### **Additional Requirements by Users**

ADDITIONAL REQUIREMENTS BY USERS	DISPOSABLE	REUSABLE		
Reusable sharps containers				
Peer-reviewed published studies confirm system's ability to reduce greenhouse gas emissions of sharps waste stream				
System allows container change-out either by healthcare facility or external contractor				
Cost benefit analysis compares current and reusable system				
Number of uses trackability				
Continuous monitoring of container wash parameters				
Automated processing of all container sizes				
Independent laboratory confirmation of decontamination process achieving Log 6 reduction of vegetative pathogens				
Internal transportation systems facilitate ease of transfer of full and clean containers between clinical unit and dock/Store				
External transportation systems facilitate ease of transfer of full and clean containers between user and processing facility		+		
After processing, the containers:				
Are subjected to a multi-point QA check				
Meet their original performance elements				
Are aesthetically clean, i.e. free of soil and organic matter, and overt marks, scuffs or abrasions.				
Processor				
<ul> <li>Has written comprehensive Risk Assessment to 1. Assess worker risks, 2. Decide what precautions are needed, 3. Prevent or adequately control sharps injury and infection/ illness exposure</li> </ul>				
<ul> <li>Has Standard Operating Procedures for operating, cleaning and servicing machine, including PPE for staff &amp; visitors</li> </ul>	T	T		
Maintains sharps injury Log		*		
Ensures injury control measures are used and maintained				
Ensures employees are informed, trained and supervised in BBP Exposure Precautions				
Has written plans and procedures to deal with accidents, incidents and emergencies				
ADDITIONAL USER REQUIREMENTS SCORE				

**MAX 40** 

**MAX 22** 

### **Additional Confirmation of Safety**

ADDITIONAL CONFIRMATION OF SAFETY		DISPOSABLE	REUSABLE			
All sharps containers						
Certified to meet comprehensive Standards requirements for Sharps Containers						
• ISO 23907-2012						
• CAN/CSA-Z316.6-14						
UN PGII Packaging	     					
• AS/NZS 4261:1994						
• ECRI 1993						
Certified Needle Penetration Force greater than 4.5 lbf / 20N						
	ADDITIONAL SAFETY SCORE					
	SAFETY SCORE	MAX 6	MAX 6			

### **Total Scores**

AD	DITIONAL CONFIRMATION OF SAFETY	DISPOSABLE	REUSABLE		
Certified to meet comprehensive Standards requirements for Sharps Containers					
1.	FDA				
2.	DOT				
3.	OSHA				
4.	ASTM				
5.	NIOSH				
6.	Additional User Requirements				
7.	Additional Safety				
	TOTAL SCORES				

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DANIELS HEALTH

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