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THREE DECADES, ONE PURPOSE.



# Warnings and Instructions for Medical Devices and Diagnostic Equipment

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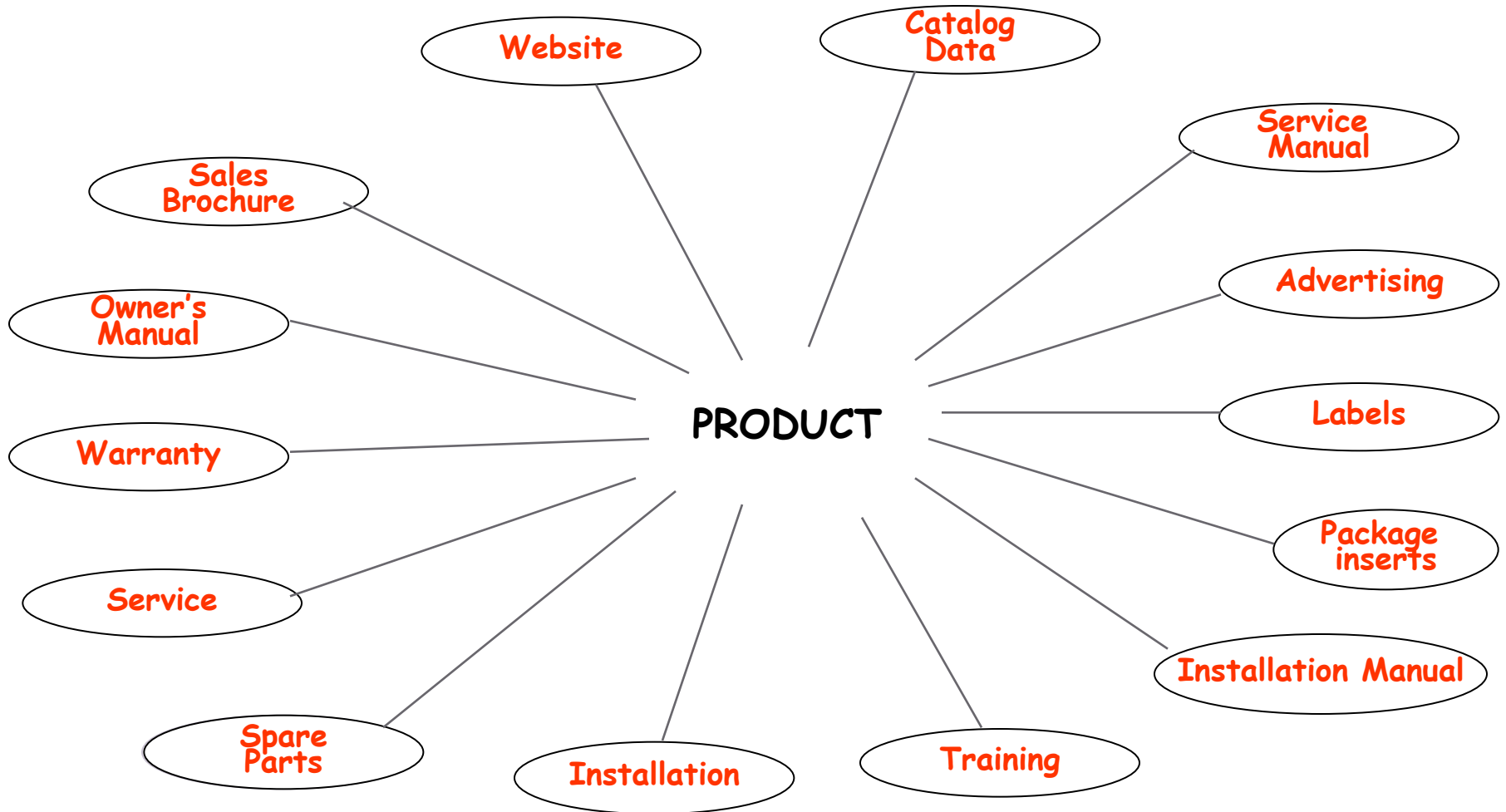
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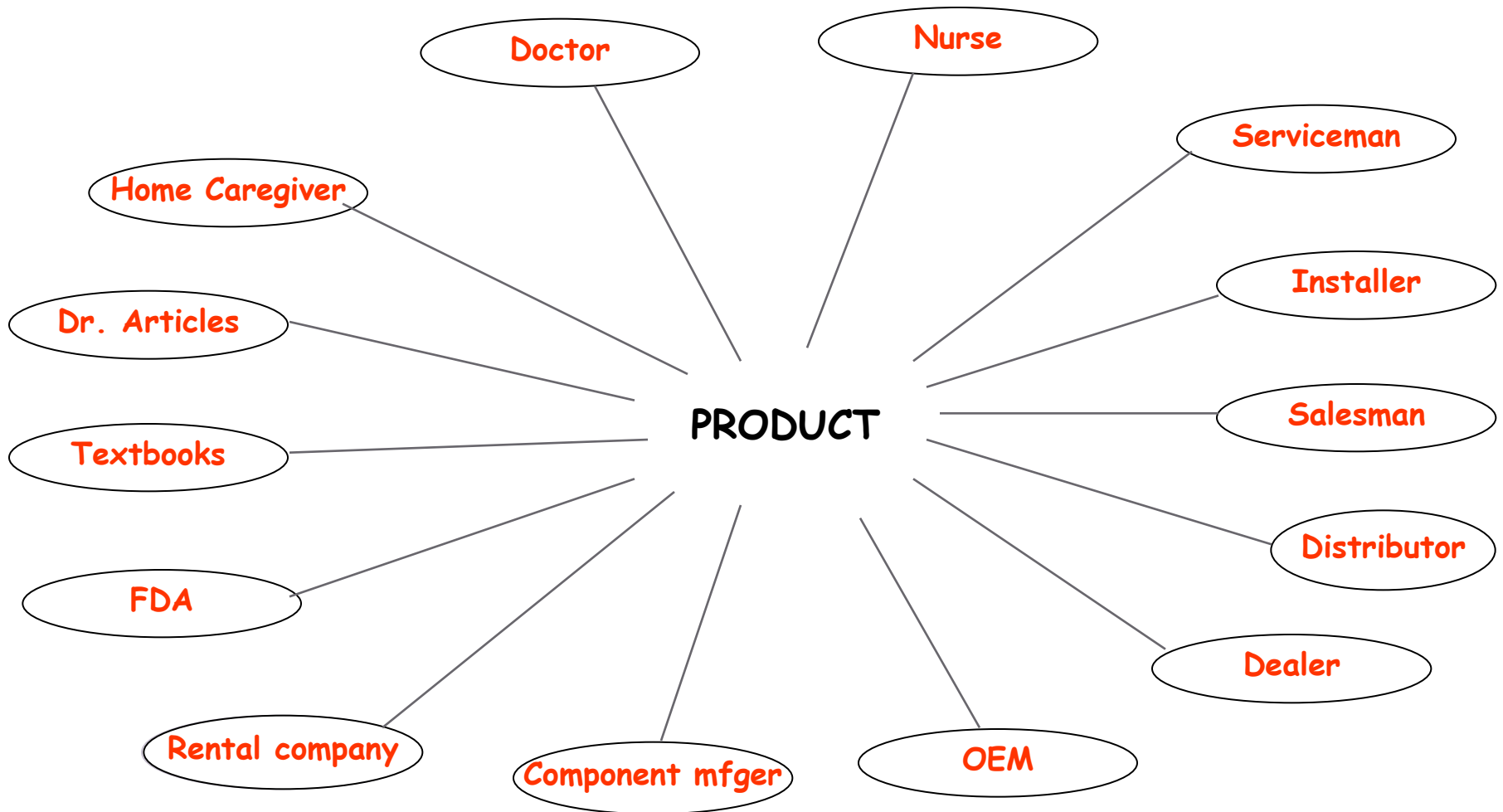
# Product Liability

Liability of a manufacturer or someone else in the chain of production and distribution for personal injury, property damage, or possibly economic loss caused by the sale or use of a product.

# What Can Create Liability



# Who Can Create Liability



# Legal requirements for device and diagnostic equipment warnings and instructions

- Common law (judges and juries)
  - State courts
  - Federal courts
- Regulatory law (Congress and FDA)
  - U.S. Codes
  - Code of Federal Regulations
  - FDA Guidances and Recommendations
- Voluntary consensus standards (ANSI, IEC, ISO, AAMI)

# Common Law

# Is compliance with FDA legal requirements a good defense in a product liability case?

- ❖ No pre-emption for 510(k) devices
- ❖ Pre-emption exists for PMA devices, but that could change
- ❖ Congress is against pre-emption
- ❖ Mere compliance may not be enough
- ❖ Government requirements are a minimum, not a maximum
- ❖ Liability if non-compliance “caused” the injury or damage. In other words, liable if compliance would have prevented the incident.

# Is compliance with voluntary standards a good defense in a product liability case?

- Not under common law. Standards are a minimum, not a maximum.
- But, good evidence of adequacy. However, not an absolute defense.
- Liability if non-compliance “caused” the injury or damage. In other words, liable if compliance would have prevented the incident.

## Safety Hierarchy - Rest. 3d

“...when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks.”

# Safety Hierarchy

- Eliminate hazard and risk from design
- Add guard, barrier, or interlock
- Add safety labels
- Provide for training and instruction
- Recommend personal protection

# Definitions

- ❖ **Warnings** alert users and consumers to the existence and nature of product risks so that they can prevent harm either by appropriate conduct during use or consumption or by choosing not to use or consume the product.
- ❖ **Instructions** inform persons how to use and consume products safely.

# Warnings Must Be Provided If...

- ❑ The product is hazardous
- ❑ The manufacturer knows or should know the product is hazardous
- ❑ The hazard is not obvious to the user
- ❑ The hazard will exist during reasonably foreseeable use or misuse

# Obvious Hazards

- ❑ Warning not required for obvious hazard
- ❑ Because product user will or should already know of its existence. Not necessary, diminish impact of other warnings.
- ❑ Decided by trier of fact
- ❑ Related to reasonably foreseeable
- ❑ Probability and severity also obvious

# Who has to be warned and instructed?

- Patient\*
- Home healthcare provider
- Parent
- Doctor
- Nurse
- Healthcare professional
- Service Technician
- Bystander

\* Affected by “learned intermediary doctrine”

# What is an adequate warning?

- It is in a form that could reasonably be expected to catch the attention of a reasonably prudent person in the circumstances of the product's use;
- The content is of such a nature as to be comprehensible to the average user; and
- It conveys a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person
- Warning's adequacy impacted by sophisticated user defense.
- Warning does not have to be effective to be adequate.

# Content of adequate warning

- Description of hazard
- Probability of hazard occurring
- Severity if occurs
- How to avoid hazard

# U.S. Law re Instructions

- A court has held that warnings, standing alone, may have no practical relevance without instructions and that instructions without warnings may not be adequate.
- In discussing the adequacy of instructions, the cases only say that manuals should be “adequate, accurate and effective” and “clear, complete and adequately communicated.”
- Whether warning goes on product or in manual is decided on a case by case basis

# Regulatory Law

# Design

- FDA requires that product be safe and effective and considers design as well as adequacy of “directions for use and warnings against unsafe use.”

# FDA: Warnings and Instructions

- 21 CFR 820 provides general requirements for labeling
- Guidance on Medical Device Patient Labeling (2001)
- FDA Quality System Manual – Chapter 11 (1996)
- Device Labeling Guidance - #G91-1 (1991)

# FDA: Warnings and Instructions

- ■ Labeling: Regulatory Requirements for Medical Devices (1989)
- ■ Human Factors Principles for Medical Device Labeling (1993)
- ■ Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care (1993)

# FDA: Warnings and Instructions

- Writing Dear Doctor Letters for Recalls of ICDs (2007)
- Guidance: Presenting Risk Information in Prescription Drug and Medical Device Promotion (2009)

# Writing Dear Doctor Letters for Recalls of ICDs (2007)

- Present safety information in consistent order
- Format for easy readability
- Include
  - Nature of malfunction
  - Scope or likelihood of problem
  - Severity
  - Recommended treatment

# Voluntary Consensus Standards

# FDA approach\*

- Compliance with recognized consensus standards is voluntary
- However, compliance can be used to show that device is safe and effective
- There are situations where standard doesn't address all safety aspects and therefore is not dispositive
- FDA maintains a database on recognized consensus standards

\*FDA Guidance on Recognition and Use of Consensus Standards (2007)

# Voluntary Standards (Common law)

- Compliance with standards is *generally* not required; however,
  - Certain FDA laws may require compliance
  - Failure to comply may have to be explained away in court
  - Could be proof of state of the art
  - May need to exceed standards

# Labeling Standards

## ❖ U.S.

- ❖ ANSI Z535 (all products where no product specific standard applies)
- ❖ IEC 60601 (medical devices)
- ❖ EN 1041

## ❖ Europe

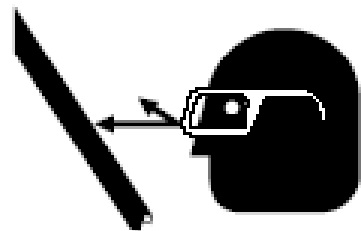
- ❖ ISO 3864 (all products except chemicals and where law requires different label)
- ❖ Product specific European Directives

# Label elements

- ❖ Signal word – Danger, Warning or Caution
- ❖ Description of hazard
- ❖ Description of consequences (severity)
- ❖ Description of probability
- ❖ How to avoid (precautions)

# Z535 Signal Words (ANSI Z535.4)

- **Danger** – will cause serious injury or death
- **Warning** – could cause serious injury or death
- **Caution** – will or could cause moderate or minor injury and property damage
- **NOTICE** – property damage only.



# WARNING

## HIGH-PRESSURE FLUID HAZARD

To prevent serious injury or death:

- High pressure oil leaks can penetrate skin causing serious injury and gangrene. If oil penetrates skin, consult a physician immediately.
- Relieve pressure on hydraulic system before servicing or disconnecting hoses.
- Wear proper hand and eye protection when searching for leaks. Use wood or cardboard instead of hands.
- Keep all components in good repair.

HH 16

# ISO 3864



# Grouped Safety Messages (ANSI Z535.6)

## CHAPTER 1. GENERAL SAFETY PRECAUTIONS

**WARNING**

Read the original equipment manufacturer's manual(s) and this handbook before servicing Tecumseh and Peerless products.

Always follow recommended service procedures. Such procedures affect the safe operation of the equipment and the safety of you and/or the operator.

Failure to follow the instructions and warnings may result in serious injury or death. Call Tecumseh Products Company at (800) 558-5402 if you have questions.

### ALWAYS PROVIDE ADEQUATE VENTILATION

To avoid serious injury or death, always ensure that you are working in a properly ventilated facility. Special precautions are required to avoid carbon monoxide poisoning.



All engine exhaust contains carbon monoxide, a deadly gas. Breathing carbon monoxide can cause headaches, dizziness, drowsiness, nausea, confusion and eventually death. Carbon monoxide is a colorless, odorless, tasteless gas which may be present even if you do not see or smell any engine exhaust.

Deadly levels of carbon monoxide can collect rapidly and you can quickly be overcome and unable to save yourself. Also, deadly levels of carbon monoxide can linger for hours or days in enclosed or poorly-ventilated areas.

If you experience any symptoms of carbon monoxide poisoning, leave the area immediately, get fresh air, and SEEK MEDICAL TREATMENT.

To prevent serious injury or death from carbon monoxide:

- ALWAYS direct engine exhaust outdoors.
- NEVER run an engine outdoors where engine exhaust can be drawn into a building through openings such as windows and doors.

### USE PROPER METHODS WHEN CLEANING

To reduce the risk of serious injury or death from fires and/or explosions, NEVER use flammable solvents (e.g., gasoline) to clean transmissions. Use a water-based, non-flammable solvent such as Tecumseh Degreaser Cleaner.



### COMPRESSED AIR PRECAUTIONS

Never use compressed air to clean debris from yourself or your clothing. When using compressed air to clean or dry transmission products:

- Wear appropriate eye protection
- Use only approved air blow nozzles
- Air pressure must not exceed 30 psi
- Shield yourself and bystanders from flying debris

Heading indicates safety-related information

Sub-headings allow easy navigation

Supplemental directive

Safety messages apply to entire document

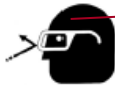
All caps only used for brief emphasis only

No Z535.4-style formatting for each message

Safety symbols

### USE PERSONAL PROTECTIVE EQUIPMENT

To avoid injury, wear protective equipment including appropriate clothing, eyewear, safety shoes and ear plugs when servicing transmission and drive products.



### STAY AWAY FROM ROTATING PARTS

Rotating parts can cause severe injury or death. Use special care when making service adjustments with covers or guards removed. Keep tools, hands, feet, hair, jewelry and clothing away from all moving parts. Replace covers and guards before operating equipment.



### STAY AWAY FROM HOT SURFACES

Parts of the equipment being serviced become extremely hot during operation and remain hot after the equipment has stopped. To avoid severe burns, stay away from hot surfaces or allow the unit to cool prior to service.



### AVOID ACCIDENTAL EQUIPMENT MOVEMENT

To prevent accidental movement of equipment, always set the parking brake. For gear-driven products that do not have a parking brake, leave equipment in gear and chock the wheels. Refer to original equipment operator manuals for additional information.

# State Of The Art Instructions

- Label on product referring to manual
- Incorporate safety information into manual
- Warning on cover to read manual
- Safety information consistent with labels, ads
- Reproduce labels in product manual
- Written for intended audience
- Delivered to customer

# High-tech ways to warn and instruct

- ❖ Interactive CDs and websites
- ❖ Readouts on LED screens
- ❖ DVDs
- ❖ Computer software
- ❖ In-service training
- ❖ Testing comprehension
  - ❖ Part of usability testing
  - ❖ Recommended in Write it Right
  - ❖ Informal focus groups versus more formal testing

# Contact information

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- <https://www.medmarc.com/WhatWeOffer/LossControl/Pages/WarningsInstructions.aspx>