ReGen Medical® RCT INDUSTRIAL

FIRST AID + WELLNESS

Decision pathway for onsite H&S teams



FEDERAL CLASSIFICATION + OSHA FIRST AID

FDA has established that RCTI falls within the federal therapeutic-massager classification. OSHA expressly recognizes massage as first aid. When RCTI is used according to its labeling and the ReGen first-aid protocol, the intervention remains massage and does not become physical therapy, chiropractic treatment, manipulation, or another medical procedure.

EMPLOYEE REPORTS DISCOMFORT OR STRAIN

MEDICAL CARE NEEDED?

Examples: severe or worsening pain, deformity, numbness or weakness, open wound, loss of function.

NO: MINOR + MASSAGE APPROPRIATE

RCTI FIRST AID PROTOCOL

1. Self-apply massage under the employer's approved protocol and device labeling.
2. Reassess symptoms and function. Stop if symptoms worsen or new concerns appear.

IMPROVED, STABLE, AND FULL DUTY?

- YES: FULL DUTY + MONITOR
- NO: MEDICAL EVALUATION

YES OR UNCERTAIN: MEDICAL FIRST

MEDICAL FIRST. WELLNESS LATER.

1. Obtain appropriate evaluation or treatment. Follow all clinician instructions and work restrictions.
2. Complete the employer's separate OSHA recordkeeping review.

WELLNESS USE ALLOWED BY CLINICIAN + SITE PROTOCOL?

- YES: RCTI ONSITE WELLNESS SUPPORT
- NO: CONTINUE CARE PLAN

WHY RCTI FITS THE FIRST AID PATHWAY

OSHA's massage rule is the legal anchor. FDA classification and the delivery protocol support the fit.

01 OSHA ANCHOR

Massage is expressly first aid

OSHA includes massage on its complete first aid list and distinguishes it from physical therapy or chiropractic treatment. [2]

02 FDA CONTEXT

Class I therapeutic massager

21 CFR 890.5660 identifies powered therapeutic massagers for minor muscle aches and pains as Class I, general controls.[1]

03 USE GUARDRAILS

Massage character stays clear

The RCTI protocol generally uses self-applied massage, with no percussion and no joint or bone manipulation, subject to labeling and site rules.[3]

THE KEY DISTINCTION — **Treatment determines first-aid status. A wellness label cannot erase medical treatment, restrictions, days away, or another OSHA recording criterion.[4]**

FOOTNOTES + USE LIMITS

[1] 21 CFR 890.5660. Class I status supplies FDA regulatory context; it does not by itself establish OSHA first-aid status or FDA approval. [2] 29 CFR 1904.7(b)(5)(ii)(M). OSHA lists massage as first aid and physical therapy or chiropractic treatment as medical treatment. [3] Self-application is typical, not required for OSHA first-aid treatment. The stated device characteristics are ReGen protocol and product representations, not separate OSHA exemptions. OSHA focuses on the treatment delivered, regardless of provider status. See 29 CFR 1904.7(b)(5)(iii)-(iv). [4] Recordability remains a separate employer determination under 29 CFR 1904.5-.7. Wellness use must remain voluntary, appropriate, consistent with clinician restrictions, device labeling, contraindications, and site policy. RCTI does not replace emergency response, diagnosis, or medical care.