Yarrow™

Instructions for Use (IFU)
YARROW™ woundbrush

ALLEVA MEDICAL

www.allevamedical.com

Rx Only

US Federal law restricts this device to sale by or on the order of a physician

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1. Introduction

The YARROW™ woundbrush is a handheld, battery-powered mechanical wound cleansing device intended for use by trained healthcare professionals. The device assists in the mechanical wound cleansing and mechanical debridement of wounds by removing surface debris such as exudate, fibrin, slough, liquefied necrotic tissue, and superficial bacterial load to support wound hygiene and wound bed preparation.

2. Indications for Use

The YARROW™ woundbrush is indicated for mechanical wound cleansing and mechanical debridement of acute and chronic open wounds healing by secondary intention in patients, under the supervision of a healthcare professional.
Mechanical cleansing and debridement assist in the removal of surface debris, fibrin, slough, liquefied necrotic tissue, and superficial bacterial load in order to support wound hygiene and wound bed preparation.

3. Intended Use

The device is intended to mechanically remove surface contaminants, fibrin, and slough from the wound bed in order to support wound hygiene and wound bed preparation. The device does not provide therapeutic energy.

4. Intended Users

The YARROW™ woundbrush is intended for use by trained healthcare professionals experienced in wound care and wound cleansing procedures, including but not limited to physicians, nurses, and wound care specialists.

5. Intended Patient Population

Patients with acute or chronic open wounds where mechanical wound cleansing or debridement is clinically indicated, including but not limited to:

- Acute wounds
- Chronic wounds
  - Arterial ulcers
  - Venous ulcers
  - Diabetic ulcers
  - Pressure ulcers
- Traumatic wounds
- Burn wounds healing by secondary intention

6. Contraindications

Do not use the YARROW™ woundbrush in the following situations:

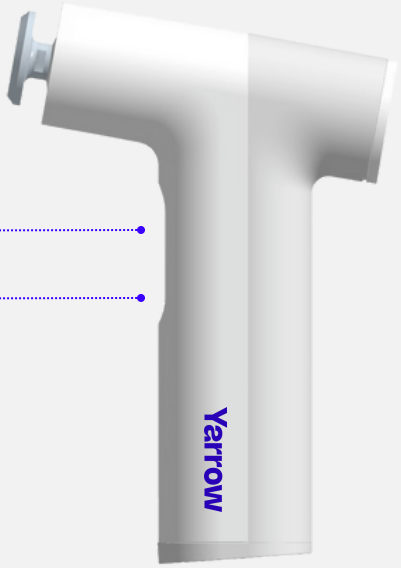
- Wounds intended to heal by primary intention
- Malignant wounds or wounds containing tumor tissue
- Patients with known hypersensitivity or allergy to silicone
- Wounds with uncontrolled active bleeding
- Direct application to exposed organs or major blood vessels

7. Package Contents

Each YARROW™ woundbrush system is supplied in an outer cardboard box containing the following components:

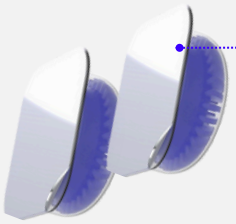
- One reusable handheld device (YARROW™ woundbrush)
- One protective case (containing the handheld device only)
- Two (2) sterile single-use Brush Heads, individually packaged
- One charging adapter and charging cable
- One Instructions for Use (manual)

All components are intended to be used exclusively with the YARROW™ woundbrush system.



ON/OFF button, Start rotating

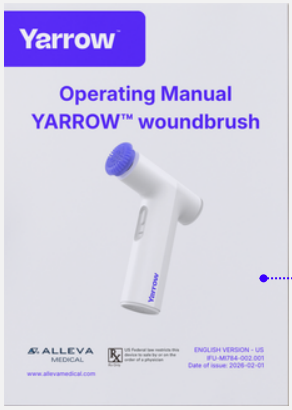
Speed setting



Two (2) sterile single-use Brush Heads,

Protective case

Charger



Manual

8. Packaging and Labeling Information

The YARROW™ woundbrush and its accessories are supplied in packaging designed to protect the device during transport and storage and to provide essential regulatory and safety information in accordance with FDA requirements (21 CFR Part 801).

8.1 Outer Packaging

The outer packaging includes:

- Product name and model identification
- Rx only statement
- Manufacturer name and address
- Lot number and/or serial number
- Storage conditions
- Applicable regulatory symbols
- QR code linking to the full Instructions for Use (U.S. version)

8.2 Inner Packaging

Inner packaging components may include:

- Protective case for the handheld device
- Charging adapter packaging
- Separate sterile peel-pack(s) for single-use Brush Heads

8.3 Sterile Brush Head Packaging

Each Brush Head is supplied in an individual sterile peel-pack labeled with:

- Product name and reference
- Sterility indication
- Single-use symbol
- Expiration date
- Lot number
- Manufacturer identification

Do not use the Brush Head if the sterile packaging is damaged, opened, or past the labeled expiration date.

8.3.1 Brush Head Variants Overview

The YARROW™ woundbrush system is compatible with different Brush Head types to support various wound locations and clinical needs.
The following sterile Brush Head variants are available:

- Basic Brush Head
- Advanced Brush Head
- Curved Brush Head

8.3.2 Brush Head Size and Design Features

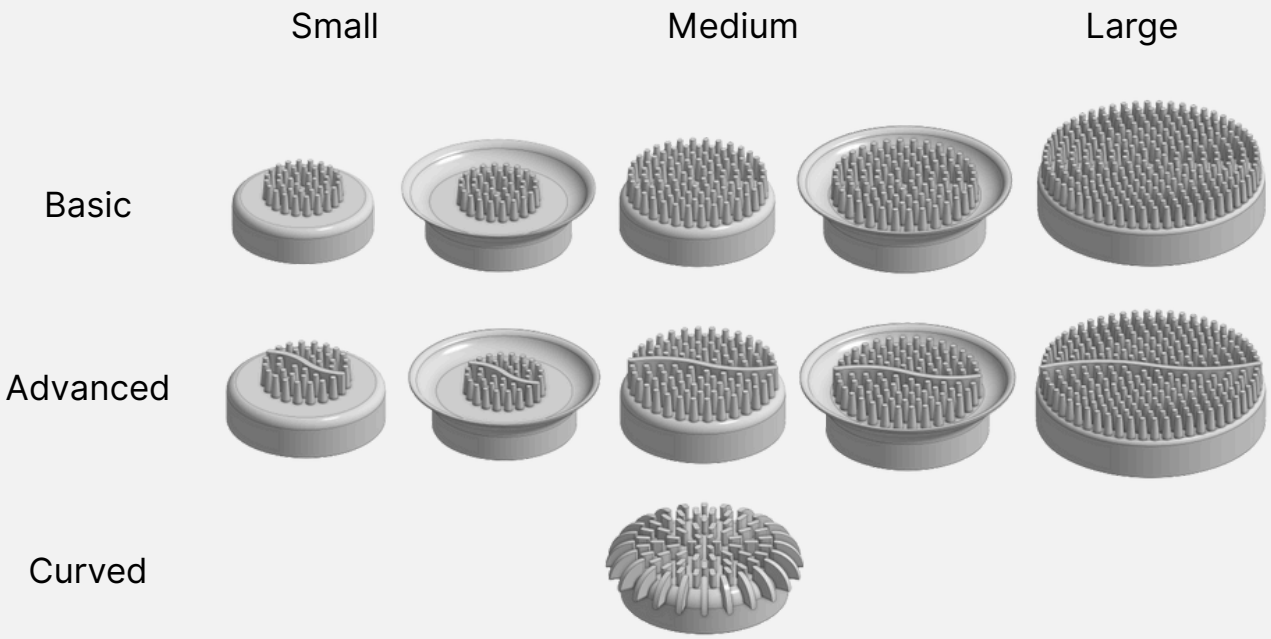
Basic and Advanced Brush Heads are available in the following sizes:

- Small
- Medium
- Large

The Small and Medium sizes of the Basic and Advanced Brush Heads are equipped with a splash guard to support controlled wound cleansing and reduce fluid dispersion during use.

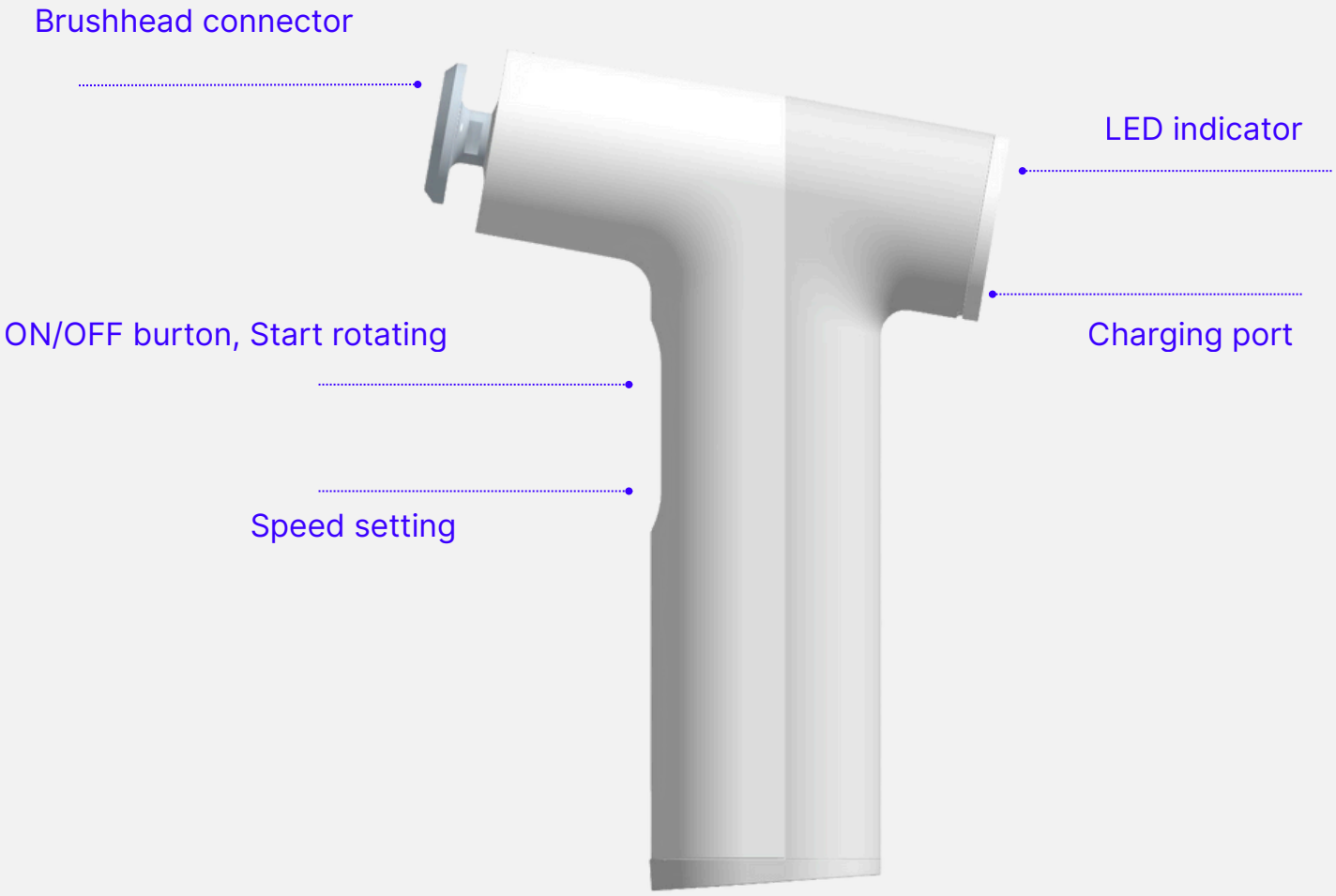
The Curved Brush Head is available in:

- Medium size only



9. Device Description and Features

The YARROW™ woundbrush system consists of a reusable handheld device and a sterile, single-use Brush Head with flexible silicone bristles. When activated, the Brush Head rotates to assist in mechanical wound cleansing and debridement. The handheld device incorporates a single control button and LED indicators to communicate operational and battery status.



10. Symbols

The following symbols may appear on the YARROW™ woundbrush, its accessories, packaging, or labeling. The symbols are used in accordance with applicable regulatory requirements and standards to provide information related to identification, safe use, and handling of the product.

	Prescription use only (21 CFR 801.109)
	Refer to the Instructions for Use
	Indicates the manufacturer
	Indicates the manufacturer's serial number for identification of the device
	Waste Electricals and Batteries
	Indicates a Type BF applied part, providing protection against electric shock
	Indicates the temperature limits to which the product can be safely exposed.
	Indicates the range of humidity to which the product can be safely exposed.
IP65	Ingress protection rating
	Do not reuse
	Sterilized using a validated sterilization method
	Indicates the date after which the product should not be used
	Indicates the manufacturer's batch code so that the batch can be identified
	Indicates the manufacturer of the product
	Do not use if the package is damaged
	Keep the product protected from moisture
	Intended for single use only

11. Warnings

- This device must only be used by trained healthcare professionals.
- Do not apply excessive pressure during wound cleansing or debridement, as this may cause tissue damage or bleeding.
- Discontinue use immediately if excessive pain, bleeding, or any adverse reaction occurs, and assess the patient before continuing treatment.
- Do not use the device on wounds with uncontrolled active bleeding.
- Do not apply the device directly to exposed organs, major blood vessels, or nerves.
- Do not operate the device while it is connected to the charging cable.
- Use only sterile, single-use Brush Heads supplied or approved by the manufacturer. Reuse may result in infection or cross-contamination.
- Do not use the device if any component appears damaged or malfunctioning.
- The device is not intended to replace surgical or sharp debridement where such procedures are clinically indicated.

12. Status Indicator (LED) Signals, Causes and Troubleshooting

LED Signal	Status Indicated	Likely Cause	Required Action
No LED illuminated	Device powered off	Device off or battery depleted	Press power button if needed
Green LED – continuous	Ready for use	Normal operation	Proceed with treatment
Green LED – flashing	Active use	Normal during cleansing	Continue use
Red LED – continuous	Low battery	Battery low	Recharge before next use
Red LED – flashing	Critically low battery	Battery nearly empty	Discontinue use and recharge
Green LED – flashing	Charging	Connected to charger	Do not use on patient
Blue LED	Device fault	Electronic malfunction	Remove from service and contact manufacturer

13. Precautions

- Always wear gloves during use and cleaning.
- Begin treatment at the lowest speed setting and adjust based on clinical judgment and patient tolerance.
- Monitor the patient throughout the procedure for signs of discomfort or adverse reaction.
- Ensure the Brush Head is securely attached prior to activation.

14. Operating Instructions

14.1 Preparation

Perform hand hygiene and don appropriate personal protective equipment.
Verify that the green LED indicator is illuminated, confirming the device is ready for use.
Inspect the sterile Brush Head packaging for integrity and expiration date.

14.2 Attaching the Brush Head

Open the sterile peel-pack without touching the bristles.
Attach the Brush Head to the handheld device while it remains inside the packaging.
Ensure the Brush Head is securely connected.

14.3 Operation

- Switch on the device using the power button.
- Begin at the lowest speed setting.
- Gently apply the rotating Brush Head to the wound bed using light pressure and controlled movements.
- Typical duration of use is approximately 1 to 3 minutes, depending on wound size and condition.
- Frequency of use may vary from once per week up to daily (7 times per week) for infected wounds, depending on wound condition and clinical judgment.

14.4 Completion and Brush Head Removal

- Switch off the device before removing the Brush Head.
- Remove the Brush Head using the sterile peel-pack to avoid direct contact with contaminated surfaces.
- Dispose of the Brush Head immediately as medical waste.

15. Cleaning and Disinfection

- Brush Heads are single-use only and must not be cleaned or reused.
- Wipe the handheld device with an approved hospital-grade disinfectant.
- Do not immerse the device or charging adapter in liquid.
- Allow all components to dry completely before storage.

16. Storage

- Store the device in its protective case in a clean, dry environment.
- Recommended storage temperature: 41–104 °F (+5 to +40 °C).
- Store Brush Heads in their original sterile packaging.

17. Disposal

- Dispose of used Brush Heads as medical waste in accordance with local, state, and federal regulations.
- Dispose of the handheld device and charging adapter in accordance with applicable electronic waste regulations.

18. Maintenance and Service Information

The YARROW™ woundbrush contains no user-serviceable parts.

- Do not attempt to open, modify, or repair the device.
- If malfunction occurs, remove from service and contact the manufacturer or authorized distributor.

20. Warranty

The YARROW™ woundbrush handheld device is covered by a limited manufacturer warranty of one (1) year from the date of purchase.
The warranty does not apply to consumables, misuse, unauthorized modification, or normal wear and tear.

21. Manufacturer Information

Manufacturer
Alleva Medical Ltd.
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Shatin, Hong Kong
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